December 21, 2021

Nobel Biocare Services AG
Bernice Jim
Head of RA Product Development and Marketed Products
Balz Zimmermann-Str. 7
Kloten, Zurich 8302
SWITZERLAND

Re: K211109
Trade/Device Name: N1™ TiUltra™ TCC Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA, PNP, QRQ
Dated: November 18, 2021
Received: November 19, 2021

Dear Bernice Jim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K211109

Device Name
N1™ TiUltra™ TCC Implant system

Indications for Use *(Describe)*
N1™ TiUltra™ TCC Implant system
N1™ TiUltra™ TCC Implant system is indicated for use in the maxilla or mandible for anchoring or supporting prosthetic teeth, in order to restore patient esthetics and chewing function. N1™ TiUltra™ TCC Implant system is indicated for single or multiple unit restorations in splinted or non-splinted applications using a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique has been achieved.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**Form 3881 (Cont.)**

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration<br>**Indications for Use** | Form Approved: OMB No. 0910-0120<br>Expiration Date: 06/30/2023<br>See PRA Statement below. |
|---|---|

510(k) Number *(if known)*

K211109

Device Name

N1™ TiUltra™ TCC Implant system

Indications for Use *(Describe) (Cont.)*

Nobel Biocare N1™ TiUltra™ TCC implants

N1™ TiUltra™ TCC Implant system is indicated for use in the maxilla or mandible for anchoring or supporting prosthetic teeth, in order to restore patient esthetics and chewing function. N1™ TiUltra™ TCC Implant system is indicated for single or multiple unit restorations in splinted or non-splinted applications using a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique has been achieved.

OsseoShaper 1 Nobel Biocare N1™ and OsseoShaper 2 Nobel Biocare N1™

The N1™ system Implant Site Preparation Tools are indicated to be used in the maxilla or mandible to prepare an osteotomy prior to placement of a Nobel Biocare N1™ TiUltra™ TCC implant.

Cover Screw Nobel Biocare N1™ TCC

To be used when applicable together with the implant during healing in order to protect the implant platform and internal threads from overgrowth of bone.

Multi-unit Abutment Xeal Nobel Biocare N1™ TCC

Multi-unit Abutment TCC is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Universal Abutment Nobel Biocare N1™ TCC

Universal abutments are indicated to support the placement of single unit, screw- retained prosthetic restorations in the maxilla or mandible.

The Universal Abutment consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment.

The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

**Form 3881 (Cont.)**

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration<br>**Indications for Use** | Form Approved: OMB No. 0910-0120<br>Expiration Date: 06/30/2023<br>See PRA Statement below. |
|---|---|

The Universal Abutment Nobel Biocare N1™ Base consist of three major parts. Specifically, the N1 Base Xeal, the Universal Abutment N1 Base, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Nobel Biocare N1™ Base Xeal™

The Nobel Biocare N1™ Base Xeal™ is indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function. It is indicated for single unit restorations and multiple unit restorations up to 6 units with less than 20° divergence to allow path of insertion.

Universal Abutment Nobel Biocare N1™ Base Tri

The Universal Abutment Nobel Biocare N1™ Base Tri is indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible.

Universal Abutment Nobel Biocare N1™ Base Tri Bridge

The Universal Abutment Nobel Biocare N1™ Base Tri Bridge is indicated to support the placement of multiple unit of up to 6 units, screwretained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.

Healing Abutment Nobel Biocare N1™ TCC

Healing abutments are indicated for use with endosseous dental implants in the maxilla or mandible for supporting single tooth to full arch denture procedures. Healing abutments Nobel Biocare N1™ TCC are indicated for use for up to 180 days.

Temporary Abutment Nobel Biocare N1™ TCC

Are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

Healing Abutment Nobel Biocare N1™ Base Tri

The Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days.

Temporary Abutment Nobel Biocare N1™ Base Tri

The Temporary Abutment Nobel Biocare N1™ Base is indicated to support the placement of single unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days.

**Form 3881 (Cont.)**

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration<br>**Indications for Use** | Form Approved: OMB No. 0910-0120<br>Expiration Date: 06/30/2023<br>See PRA Statement below. |
|---|---|

Temporary Abutment Nobel Biocare N1™ Base (Bridge)

The Temporary Abutment Nobel Biocare N1™ Base Bridge is indicated to support the placement of multiple unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days for implants with less than 20° overall divergences to allow path of insertion.

IOS Healing Abutment Nobel Biocare N1™ Base Tri

The IOS Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days. In combination with intraoral scanner the IOS Healing Abutment can be used to confirm the location, position, and orientation of the Nobel Biocare N1™ Base Xeal™, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM.

Clinical Screw Nobel Biocare N1™ Base and Prosthetic Screw Nobel Biocare N1™ Base

The Clinical and Prosthetic Screw are to be directly connected to the dental implant, abutment or framework, intended for use as an aid in prosthetic rehabilitation.

Clin Screw Multi-unit Abut Nobel Biocare N1™ TCC and Clinical Screw Nobel Biocare N1™ TCC

Clinical Screws are to be directly connected to the dental implant, abutment or framework, intended for use as an aid in prosthetic rehabilitation.

**510(k) Notification K211109**

**Submitter:**

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**Submitted by:**

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**Contact Person:** Bernice Jim, Ph.D.
**E-Mail:** regulatory.affairs@nobelbiocare.com
**Date Prepared:** 21 December 2021

**Device:**

**Trade Name:** N1™ TiUltra™ TCC Implant system
**Manufacturer:** Nobel Biocare AB
**Generic/Common Name:** Dental Implants
**Regulation Name:** Endosseous Dental Implant
**Regulation Number:** 21 CFR§872.3640
**Regulatory Class:** II
**Product Code:** DZE
**Secondary Product Codes:** NHA, PNP, QRQ

**Predicate Devices:**

The predicate and reference devices used in this 510(k) submission are described in Table 5.1.

**Table 5.1: Predicate and Reference Devices for the N1™ TiUltra™ TCC Implant system (N1™ system)**

| | Device | 510(k) | Manufacturer |
|---|---|---|---|
| Primary Predicate | NobelActive | K142260 | Nobel Biocare AB |
| Reference #1 | TiUltra Implants and Xeal Abutments | K202344 | Nobel Biocare AB |
| Reference #2 | NobelActive Wide Platform (WP) | K133731 | Nobel Biocare AB |
| Reference #3 | On1 Concept | K161655 | Nobel Biocare AB |
| Reference #4 | Branemark Novum | K000018 | Nobel Biocare UAS Inc. |
| Reference #5 | Universal Base Conical Connection (CC) | K200040 | Nobel Biocare AG |
| Reference #6 | On1 Universal Abutment | K181869 | Nobel Biocare AB |
| Reference #7 | Multi-unit Abutment Plus | K161416 | Nobel Biocare AB |
| Reference #8 | Nobel Biocare Dental Implant Systems Portfolio - MR Conditional | K212125 | Nobel Biocare AG |

In compliance with the FDA Guidance Document entitled, "*Bundling Multiple Devices or Multiple Indications in a Single Submission*," issued June 22, 2007, Nobel Biocare has prepared a single submission for the N1™ TiUltra™ TCC Implant system because the submission represents a system of devices used together for a dental procedure which has similar supportive data, and one FDA review division will be involved.

## Device Description

N1 TiUltra TCC Implant system is composed of implants, implant site preparation tools, abutments, and abutment screws. Table 5.2 provides the Device Lines that when used together form the N1 TiUltra TCC Implant system.

**Table 5.2: Devices Included in this 510(k) Submission**

| Subject Device | Item No. | Device Lines | Description |
|---|---|---|---|
| N1™ TiUltra™ TCC Implant system | 1 | Nobel Biocare N1™ TiUltra™ TCC implants | Endosseous dental implant |
| | 2 | OsseoShaper | Instruments for bone preparation |
| | 3 | Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC | Endosseous dental abutment |
| | 4 | Universal Abutments Nobel Biocare N1™ | Endosseous dental abutment |
| | 5 | Temporary Abutments | Endosseous dental abutment |
| | 6 | Screws | Screws for endosseous dental abutments |

The device description for the seven Device Lines are as follows:

Nobel Biocare N1™ TiUltra™ TCC implants (Item 1):

N1 TiUltra TCC Implant system consists of a dental implant (i.e., Nobel Biocare N1™ TiUltra™ TCC implants) featuring the Tri-oval Conical Connection (TCC), which is characterized by a tri-oval shaped coronal zone and a round, moderately tapered body. It is intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.

The Nobel Biocare N1 TiUltra TCC implants Device Line also includes the Cover Screw Nobel Biocare N1™ TCC ("Cover Screw"), which is a Device Component that covers the implant platform and prevents tissue overgrowth during the healing phase of the placed implant. The threaded portion of the Cover Screw fits inside the internal thread of the implant, while the head of the Cover Screw covers the inner surface of the implant (i.e., the implant connection).

OsseoShaper (Item 2):

The OsseoShapers are rotating implant site preparation tools to be used at low speed (50rpm) without irrigation. The implant can be placed as soon as the OsseoShaper 1 Nobel Biocare N1™ ("OsseoShaper 1") has reached the desired depth and position in accordance with the preoperative planning at a torque value of <40 Ncm. The

OsseoShaper 2 Nobel Biocare N1™ ("OsseoShaper 2") is intended to be used when the OsseoShaper 1 does not reach the desired depth and position in accordance with the preoperative planning and at a torque of <40 Ncm. The OsseoShapers work in conjunction with traditional implant placement accessories not subject to this submission (e.g., Guided Pilot Drill).

Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC (Item 3):

The Multi-unit Abutments Xeal™ Nobel Biocare N1™ TCC are transmucosal abutments used for multiple unit screw retained restorations. The Multi-unit Abutments Xeal Nobel Biocare N1 TCC are available in Narrow Platform (NP) and Regular Platform (RP), feature a tri-oval conical connection (TCC), and are compatible with the Nobel Biocare N1 TiUltra TCC implants.

Universal Abutments Nobel Biocare N1™ (Item 4):

The Universal Abutment Nobel Biocare N1™ Device Line consists of the following Device Components:

- Universal Abutment Nobel Biocare N1™ TCC
- Universal Abutment Nobel Biocare N1™ Base Tri
- Universal Abutment Nobel Biocare N1™ Base Tri (Bridge)
- Nobel Biocare N1™ Base Xeal™ TCC Tri

The Universal Abutment Nobel Biocare N1™ Device Line are pre-manufactured dental implant abutments which can be either connected directly to a Nobel Biocare N1 TiUltra TCC implant, featuring the tri-oval conical connection, or to a Nobel Biocare N1 Base Xeal TCC Tri to support the placement of a screw-retained dental prosthesis.

The digital workflow requires the use of the following equipment and materials:

| **Equipment / Material** | **Minimum Requirements** |
|---|---|
| Scanner | Kavo LS3, 3Shape Trios, or other scanners with accuracy equal or higher than 6.9 µm |
| Design Software | DTX Studio Lab<br>(The Implant Libraries are automatically included in the software installer) or<br>3Shape Dental Designer<br>(The Implant Libraries are obtained via the 3Shape server in the software). |
| Restorative Material | Nacera Pearl Doceram Medical Ceramics<br>Minimum wall thickness allowed: ≤ 0.5 mm |
| Milling Unit | Roland DWX-52D |

The bonding procedure requires the use of following materials:

| | |
|---|---|
| Primer | Monobond Plus by Ivoclar Vivadent |
| Adhesive | Multilink Hybrid by Ivoclar Vivadent |
| Glycerin Gel | Liquid Strip by Ivoclar Vivadent |

Temporary Abutments (Item 5):

The Temporary Abutments Device Line consists of the following abutments:

- Healing Abutment Nobel Biocare N1™ TCC
- Healing Abutment Nobel Biocare N1™ Base Tri
- Temporary Abutment Nobel Biocare N1™ TCC
- Temporary Abutment Nobel Biocare N1™ Base Tri
- Temporary Abutment Nobel Biocare N1™ Base (Bridge)
- IOS Healing Abutment Nobel Biocare N1™ Base Tri

The Healing Abutment Nobel Biocare N1 TCC and Healing Abutment Nobel Biocare N1 Base Tri are pre-manufactured dental implant abutments which can be either connected directly to a Nobel Biocare N1 TiUltra TCC implant, for the Healing Abutment Nobel Biocare N1 TCC, or to a Nobel Biocare N1 Base Xeal TCC Tri, for the Healing Abutment Nobel Biocare N1 Base Tri, to support healing of the surrounding soft tissue. The TCC connection interface is featured on the Healing Abutment Nobel Biocare N1 TCC, whereas the Healing Abutments Nobel Biocare N1 Base Tri feature the N1™ Prosthetic Connection.

The Temporary Abutment Nobel Biocare N1 TCC is a pre-manufactured dental implant abutment which can be either connected directly to a Nobel Biocare N1 TiUltra TCC implant, for the Temporary Abutment Nobel Biocare N1 TCC, or to a Nobel Biocare N1 Base Xeal TCC Tri to support the placement of a temporary dental prosthesis. The Temporary Abutment Nobel Biocare N1 Base Tri and Temporary Abutment Nobel Biocare N1 Base (Bridge) are pre-manufactured dental implant abutments which are placed on top of the Nobel Biocare N1 Base Xeal TCC Tri to support the placement of a temporary dental prosthesis. The TCC connection interface is featured on the Temporary Abutment Nobel Biocare N1 TCC whereas the Temporary Abutment Nobel Biocare N1 Base Tri and Temporary Abutment Nobel Biocare N1 Base Tri (Bridge) feature the N1™ Prosthetic Connection.

The IOS Healing Abutment Nobel Biocare N1 Base Tri is a pre-manufactured dental implant abutment which can be connected to a Nobel Biocare N1 Base Xeal TCC Tri to support healing of the surrounding soft tissue and to facilitate the transfer of an intra-oral location of the Nobel Biocare N1 Base Xeal TCC Tri from the patient's jaw to the relative position on a master cast in the dental laboratory using an intra-oral scanning procedure. The connection interface for the IOS Healing Abutment Nobel Biocare N1 Base Tri is the N1™ Prosthetic Connection.

Screws (Item 6):

The Nobel Biocare N1 TiUltra TCC Implant system contains the following abutment screws:

- Clin Screw Multi-unit Abut Nobel Biocare N1™ TCC
- Prosthetic Screw Nobel Biocare N1™ Base
- Clinical Screw Nobel Biocare N1™ Base
- Clinical Screw Nobel Biocare N1™ TCC

Clinical and Prosthetic Screws of the N1 system are pre-manufactured dental implant screws designed to fix dental prostheses or dental implant system components such as implant abutments and implant healing abutments to an endosseous dental implant or to an endosseous dental abutment.

## Indications for Use:

N1™ TiUltra™ TCC Implant system

N1™ TiUltra™ TCC Implant system is indicated for use in the maxilla or mandible for anchoring or supporting prosthetic teeth, in order to restore patient esthetics and chewing function. N1™ TiUltra™ TCC Implant system is indicated for single or multiple unit restorations in splinted or non-splinted applications using a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique has been achieved.

Nobel Biocare N1™ TiUltra™ TCC implants

N1™ TiUltra™ TCC Implant system is indicated for use in the maxilla or mandible for anchoring or supporting prosthetic teeth, in order to restore patient esthetics and chewing function. N1™ TiUltra™ TCC Implant system is indicated for single or multiple unit restorations in splinted or non-splinted applications using a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique has been achieved.

OsseoShaper 1 Nobel Biocare N1™ and OsseoShaper 2 Nobel Biocare N1™

The N1™ system Implant Site Preparation Tools are indicated to be used in the maxilla or mandible to prepare an osteotomy prior to placement of a Nobel Biocare N1™ TiUltra™ TCC implant.

Cover Screw Nobel Biocare N1™ TCC

To be used when applicable together with the implant during healing in order to protect the implant platform and internal threads from overgrowth of bone.

Multi-unit Abutment Xeal Nobel Biocare N1™ TCC

Multi-unit Abutment TCC is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Universal Abutment Nobel Biocare N1™ TCC

Universal abutments are indicated to support the placement of single unit, screw- retained prosthetic restorations in the maxilla or mandible.

The Universal Abutment consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment.

The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

The Universal Abutment Nobel Biocare N1™ Base consist of three major parts. Specifically, the N1 Base Xeal, the Universal Abutment N1 Base, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Nobel Biocare N1™ Base Xeal™

The Nobel Biocare N1™ Base Xeal™ is indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function. It is indicated for single unit restorations and multiple unit restorations up to 6 units with less than 20° divergence to allow path of insertion.

Universal Abutment Nobel Biocare N1™ Base Tri

The Universal Abutment Nobel Biocare N1™ Base Tri is indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible.

Universal Abutment Nobel Biocare N1™ Base Tri Bridge

The Universal Abutment Nobel Biocare N1™ Base Tri Bridge is indicated to support the placement of multiple unit of up to 6 units, screwretained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.

Healing Abutment Nobel Biocare N1™ TCC

Healing abutments are indicated for use with endosseous dental implants in the maxilla or mandible for supporting single tooth to full arch denture procedures. Healing abutments Nobel Biocare N1™ TCC are indicated for use for up to 180 days.

Temporary Abutment Nobel Biocare N1™ TCC

Are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

Healing Abutment Nobel Biocare N1™ Base Tri

The Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days.

Temporary Abutment Nobel Biocare N1™ Base Tri

The Temporary Abutment Nobel Biocare N1™ Base is indicated to support the placement of single unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days.

Temporary Abutment Nobel Biocare N1™ Base (Bridge)

The Temporary Abutment Nobel Biocare N1™ Base Bridge is indicated to support the placement of multiple unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days for implants with less than 20° overall divergences to allow path of insertion.

IOS Healing Abutment Nobel Biocare N1™ Base Tri

The IOS Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days. In combination with intraoral scanner the IOS Healing Abutment can be used to confirm the location, position, and orientation of the Nobel Biocare N1™ Base Xeal™, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM.

Clinical Screw Nobel Biocare N1™ Base and Prosthetic Screw Nobel Biocare N1™ Base

The Clinical and Prosthetic Screw are to be directly connected to the dental implant, abutment or framework, intended for use as an aid in prosthetic rehabilitation.

Clin Screw Multi-unit Abut Nobel Biocare N1™ TCC and Clinical Screw Nobel Biocare N1™ TCC

Clinical Screws are to be directly connected to the dental implant, abutment or framework, intended for use as an aid in prosthetic rehabilitation.

## Comparison of Technological Characteristics

### Nobel Biocare N1 TiUltra TCC implants

The subject device, Nobel Biocare N1 TiUltra TCC implants have the same intended use and similar Indications for Use as NobelActive – K142260 (Primary Predicate) as the only difference is choice of similar wording. The Subject Device and Primary Predicate are endosseous dental implants to support prosthetic devices in order to restore patient esthetics and chewing function. Therefore, the devices are substantially equivalent in consideration of the intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices have the same material and have the same surface treatment. In addition, both devices have the same range of implant lengths, implant diameters, and platform compatibility.

There are technological differences (i.e., connection interface, macro design, surface topography, surface preservation, Instructions for Use, and packaging) between the Nobel Biocare N1 TiUltra TCC implants, and the Primary Predicate, however, these differences do not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical and clinical testing.

### Cover Screw

The Cover Screw has the same intended use and similar Indications for Use as the cover screws for NobelActive – K142260 (Primary Predicate), as the only differences are the choice of similar wording. Both devices are intended to be connected to a dental implant in order to protect the implant during the healing phase. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices have the same material, gingival height, packaging, sterilization characteristics, and a similar range in diameters.

There are technological differences (i.e., design, connection interface and surface treatment) between the Cover Screw and the Primary Predicate however, these differences do not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical testing.

### OsseoShapers

The OsseoShapers have the same intended use and similar Indications for Use as the Screw Tap from NobelActive – K142260 (Primary Predicate), as both devices are intended to be used to cut into the maxilla or mandible to create an osteotomy for endosseous dental implant placement. The only differences are the choice of similar wording. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices have the same tip design, are compatible with ISO 1797 Type 1 handpiece connections, have insertion depth markings, and use no irrigation during transient surgical use.

There are technological differences (i.e., design, materials and surface treatment, drill speed, reusability, and packaging) between the OsseoShapers and the Primary Predicate, however, these differences do not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical testing.

### Multi-unit Abutment Xeal Nobel Biocare N1 TCC

The Multi-unit Abutment Xeal Nobel Biocare N1 TCC has the same intended use and Indications for Use as the Multi-unit Abutment Xeal™ from TiUltra Implants and Xeal Abutments – K202344 (Reference #1). Both abutment devices are premanufactured prosthetic components directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices are composed of the same material, have the same range of device lengths, widths, and platforms, and feature the Xeal surface with the soluble salt (protective) layer.

There is only one technological difference (i.e., connection interface) between the Multi-unit Abutment Xeal Nobel Biocare N1 TCC and Reference #1, however, this difference does not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical testing.

**Universal Abutments Nobel Biocare N1 (UA N1)**

The UA N1 has the same intended use as the On1 Base Xeal™ and Multi-unit Abutment Xeal™ from TiUltra Implants and Xeal Abutments – K202344 (Reference #1), the only difference is the choice of similar wording. Both devices are abutment components which are intended to be used with endosseous dental implants and be used as an aid in prosthetic rehabilitation. In addition, both devices have similar Indications for Use as it describes the number of abutment major parts and the associated workflow. Specifically, both Indications for Use indicate for one or more titanium base elements and mesostructure components making up a two- or multi-piece abutment. Further, both abutment systems integrate multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The Indications for Use of Universal Base Conical Connection (CC) – K200040 (Reference #5) is also similar as it indicates for a two major part abutment with the same digital dentistry workflow. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices have the same compatible implant platforms, titanium (Ti)-base material, abutment fixation, maximum abutment angulation, surface treatment, and abutment packaging.

There are technological differences (i.e., connection interface, abutment design, wall thickness circular/margin, abutment width, design workflow, manufacturing workflow, surface topography, surface preservation, and sterilization) between the UA N1 and Reference #1, however, these differences do not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical testing.

**Temporary Abutments**

The Temporary Abutments have the same intended use as the Healing Abutment Conical Connection WP and Temporary Snap Abutment Engaging Conical Connection WP from NobelActive Wide Platform (WP) – K133731 (Reference #2), as both abutment devices are premanufactured prosthetic components directly connected to an endosseous dental implant and or abutment base and is intended for use as an aid in prosthetic rehabilitation. In addition, the Indications for Use of the Temporary Abutments are similar to Reference #2 as both devices use similar wording. Temporary Abutments also include references to implant duration and digital workflows are represented in the Indications for Use of the On1 IOS Healing Cap from On1 Universal Abutment – K181869 (Reference #6) which has the same intended use as the Temporary Abutments and Reference #2. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices have the same abutment diameter range, abutment angulation, packaging, and sterilization characteristics.

There are technological differences (i.e., material, post and gingival height, compatible implant platform, connection interface, and surface treatment) between the Temporary Abutments and Reference #2, however, these differences do not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical bench testing.

**Screws**

The Screws have the same intended use as the On1™ Clinical Screw, and On1™ Prosthetic Screw from On1 Concept – K161655 (Reference #3), as they are all screws intended to secure dental abutments to dental implants, dental abutments to dental abutments, or dental abutments to final restoration. In addition, the Indications for Use are similar to Reference #3 and the same as the Clinical Screws MUA from Multi-unit Abutment Plus – K161416 (Reference #7). The differences between the indications are a choice of similar wording. The differences do not affect the shared intended use between the devices. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. Both devices have the same material, range of surface treatments, range of anatomical sites, packaging, and sterilization parameters.

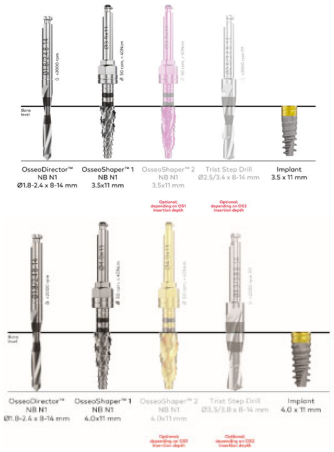
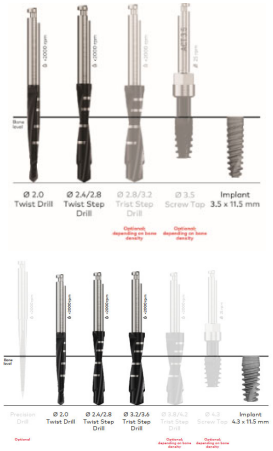
There are technological differences (i.e., shaft diameter, total length, connection interface, abutment compatibility) between the Screws and Reference #3, however, these differences do not affect the shared intended use, between the devices, nor raise different questions of substantial equivalence as demonstrated by non-clinical testing.

Substantial Equivalence Tables

| **Substantial Equivalence Table for N1 TiUltra TCC implants** | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive – K142260 (Primary Predicate)** | **Reference Device**<br>**TiUltra Implants and Xeal Abutments – K202344 (Reference #1)** | **Comparison** |
| **Device** | Nobel Biocare N1™ TiUltra™ TCC implants | NobelActive implants | NobelActive® TiUltra™ | -- |
| **Pictorial Representation** |  |  |  | -- |
| **Regulatory Number/ Device Classification Name** | 21 CFR§872.3640<br>Endosseous dental implant | 21 CFR§872.3640<br>Endosseous dental implant | 21 CFR§872.3640<br>Endosseous dental implant | Same as the Primary Predicate. |
| **Product Code** | DZE | DZE | DZE | Same as the Primary Predicate. |
| **Intended Use** | Intended for use in the maxilla or mandible for supporting dental prostheses to restore patient esthetics and chewing function. | NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. | Nobel Biocare's TiUltra implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients. | The same intended use as the Primary Predicate expressed through a similar choice of words. |
| **Indications for Use** | N1™ TiUltra™ TCC Implant system is indicated for use in the maxilla or mandible for anchoring or supporting prosthetic teeth, in order to restore patient esthetics and chewing function. N1™ TiUltra™ TCC Implant system is indicated for single or multiple unit restorations in splinted or non-splinted applications using a 2-stage | NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.<br>NobelActive® implants are indicated for single or multiple unit restorations in splinted or | NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.<br>NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or | Similar Indications for Use as the Primary Predicate expressed through a similar choice of words. |

| Substantial Equivalence Table for N1 TiUltra TCC implants | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive – K142260 (Primary Predicate)** | **Reference Device**<br>**TiUltra Implants and Xeal Abutments – K202344 (Reference #1)** | **Comparison** |
| | or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique has been achieved. | non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.<br>NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.<br>NobelActive® 3.0 implants are indicated for single unit restorations only. | non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.<br>NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.<br>NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only. | |
| **Implant Length** | 7.0, 9.0, 11.0, 13.0 mm | 7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 mm | 7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 mm | The range of implant lengths falls within that of the Primary Predicate. |
| **Implant Diameter** | 3.5, 4.0 mm | 3.0, 3.5, 4.3, 5.0, 5.5 mm | 3.0, 3.5, 4.3, 5.0, 5.5 mm | The range of implant diameters falls within that of the Primary Predicate. |
| **Platform Compatibility** | Narrow Platform (NP)<br>Regular Platform (RP) | 3.0 Platform<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP) | 3.0 Platform<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP) | The range of implant platforms falls within that of the Primary Predicate. |
| **Connection Interface** | Nobel Biocare Tri-oval Conical Connection (TCC) | Nobel Biocare Internal Conical Connection (CC) | Nobel Biocare Internal Conical Connection (CC) | Serves the same function as the Primary Predicate's connection interface. The differences do not raise different questions of substantial equivalence and is substantiated through fatigue testing. |
| **Macro Design** | Tapered implant with coronal tri-oval macro shape, cutting flutes and single lead threads | Tapered implant with back-tapered coronal design, apical reverse-cutting flutes and double lead threads | Tapered implant with back-tapered coronal design, apical reverse-cutting flutes and double lead threads | Serves the same function as the Primary Predicate's macro design. The differences do not raise different questions of substantial equivalence, as demonstrated by torque testing. |

| **Substantial Equivalence Table for N1 TiUltra TCC implants** | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive – K142260 (Primary Predicate)** | **Reference Device**<br>**TiUltra Implants and Xeal Abutments – K202344 (Reference #1)** | **Comparison** |
| **Material** | Commercially pure titanium (grade 4) according to ASTM F67 | Commercially pure titanium (grade 4) according to ASTM F67 | Commercially pure titanium (grade 4) according to ASTM F67 | Same as the Primary Predicate. |
| **Surface Treatment** | Anodic oxidation | Machined on collar and inside the connection (NP and RP)<br>Anodic oxidation on collar and inside the connection (WP) | Anodic oxidation | Same as the Primary Predicate's WP platform implant. |
| **Surface Topography** | TiUltra – Three level surface:<br>Level 0 (collar):<br>Sa (area roughness) = 0.5 ± 0.3 µm<br>Thickness (Thk) = 0.166 ± 0.008 µm<br>Level 1 (transition):<br>Sa = 0.8 ± 0.3 µm<br>Thk = 7.5 ± 0.3 µm<br>Level 2 (body):<br>Sa = 1.5 ± 0.4 µm<br>Thk = 12.0 ± 1.2 µm | TiUnite – Single level surface:<br>Sa = 1.2 ± 0.5 µm<br>Thk = 12.5 ± 2.5 µm | TiUltra – Three level surface:<br>Level 0 (collar):<br>Sa (area roughness) = 0.5 ± 0.3 µm<br>Thickness (Thk) = 0.166 ± 0.008 µm<br>Level 1 (transition):<br>Sa = 0.8 ± 0.3 µm<br>Thk = 7.5 ± 0.3 µm<br>Level 2 (body):<br>Sa = 1.5 ± 0.4 µm<br>Thk = 12.0 ± 1.2 µm | Same as reference device (Reference #1). The differences do not raise different questions of substantial equivalence, as demonstrated by fatigue and biocompatibility testing. |
| **Surface Preservation** | Soluble salt (protective) layer:<br>Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt | None | Soluble salt (protective) layer:<br>Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt | Same as reference device (Reference #1). The differences do not raise different questions of substantial equivalence, as demonstrated by fatigue, biocompatibility, and packaging and sterilization testing. |

| Substantial Equivalence Table for N1 TiUltra TCC implants | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive – K142260 (Primary Predicate)** | **Reference Device**<br>**TiUltra Implants and Xeal Abutments – K202344 (Reference #1)** | **Comparison** |
| **Instructions for Use (Drill Protocol)** | Two to four Step Drill Protocol<br>  | One to six Step Drill Protocol<br>  | N/A – The ISP protocol used for this device is the same as K142260. | The Drill Protocol is similar to the Primary Predicate and Reference #1. The differences do not raise different questions of substantial equivalence, as demonstrated by heat generation testing, torque insertion testing, and performance data from animal and clinical studies. |
| **Packaging** | N1 TiUltra TCC implants are co-packaged with the corresponding OsseoShaper 1 Nobel Biocare N1™ in a polyethylene terephthalate glycol (PETG) Blister tray heat sealed with a Tyvek® lid (sterile barrier) inside a cardboard box (protective packaging). | Polyethylene terephthalate (PET) vial with high density polyethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister tray heat sealed with a Tyvek® lid (2nd sterile barrier) inside a cardboard box (protective packaging). | Polyethylene terephthalate (PET) vial with high density polyethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister tray heat sealed with a Tyvek® lid (2nd sterile barrier) inside a cardboard box (protective packaging | N1 TiUltra TCC implants have similar packaging to the Primary Predicate. The differences do not raise different questions of substantial equivalence as demonstrated by packaging validation. |
| **Sterilization** | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Same as the Primary Predicate. |

| Substantial Equivalence Table for the Cover Screw | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive – K142260 (Primary Predicate)** | **Reference Device**<br>**On1 Concept – K161655 (Reference #3)** | **Comparison** |
| **Device** | Cover Screw Nobel Biocare N1™ TCC | Cover screws | On1 Clinical Screw | -- |
| **Pictorial Representation** |  |  |  | -- |
| **Regulatory Number / Device Classification Name** | 21 CFR§872.3640<br>Endosseous dental implant | 21 CFR§872.3640<br>Endosseous dental implant | 21 CFR§872.3630<br>Endosseous dental implant abutment | Same as the Primary Predicate. |
| **Product Code** | DZE | DZE | NHA | Same as the Primary Predicate. |
| **Intended Use** | Dental implant Cover Screws are to be used in the upper or lower jaw connected to the endosseous implant to protect the internal threads and implant head during the healing phase. | Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing. | Intended for fixation of the On1 Base. | The same intended use as the Primary Predicate expressed through a similar choice of words. |
| **Indications for Use** | To be used when applicable together with the implant during healing in order to protect the implant platform and internal threads from overgrowth of bone. | Cover screws are indicated for use with implants placed in the maxilla, mandible, or zygomatic bone, as per the indications for the respective implant system. | The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. | Similar Indications for Use as the Primary Predicate expressed through a similar choice of words. |
| **Design** | 2-piece pre-assembled | 1-piece | 1-piece | Serves the same function as the Primary Predicate. Provided pre-assembled into 1-piece. The differences do not raise different questions of substantial equivalence. |
| **Diameter** | 3.2, 3.4 mm | 3.0, 3.5, 3.9, 5.1 mm | 1.185, 1.475 mm | The range of cover screw diameters falls within that of the Primary Predicate. |
| **Gingival Height** | 0.4 mm | 0.4 mm | -- | Same as the Primary Predicate. |

| **Substantial Equivalence Table for the Cover Screw** | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive – K142260 (Primary Predicate)** | **Reference Device**<br>**On1 Concept – K161655 (Reference #3)** | **Comparison** |
| **Connection Interface** | Nobel Biocare Tri-oval Conical Connection (TCC) | Nobel Biocare Internal Conical Connection (CC) | Nobel Biocare Internal Conical Connection (CC) | Serves the same function as the Primary Predicate's connection interface. The differences do not raise different questions of substantial equivalence. |
| **Surface treatment** | Anodization<br>DLC Coating (screw interface) | Anodization | Anodization<br>DLC Coating (screw interface) | Similar to the Primary Predicate and reference device (Reference #3). The differences do not raise different questions of substantial equivalence. |
| **Material** | Titanium-aluminum-vanadium alloy<br>(ASTM F136 and ISO 5832-3) | Titanium-aluminum-vanadium alloy<br>(ASTM F136 and ISO 5832-3) | Titanium-aluminum-vanadium alloy<br>(ASTM F136 and ISO 5832-3) | Same as Primary Predicate |
| **Packaging** | Thermoformed PETG blister tray and sealed with a peelable medical paper lid | Thermoformed PETG blister tray and sealed with a peelable medical paper lid | Thermoformed PETG blister tray and sealed with a peelable medical paper lid | Same as the Primary Predicate. |
| **Sterilization** | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Same as the Primary Predicate. |

| Substantial Equivalence OsseoShapers | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive**<br>**(K142260 – Primary Predicate)** | **Reference Device**<br>**Branemark Novum**<br>**(K000018 – Reference #4)** | **Comparison** |
| **Device** | OsseoShaper 1 Nobel Biocare N1™<br>OsseoShaper 2 Nobel Biocare N1™ | Screw Tap | Screw Tap ø5mm | -- |
| **Graphic Illustration** | OsseoShaper 1 Nobel Biocare N1™<br>  <br>OsseoShaper 2<br>  |  |  | -- |
| **Regulatory Number/ Device Classification Name** | 21 CFR§872.3980<br>Endosseous dental implant accessories | 21 CFR§872.3640<br>Endosseous dental implant | 21 CFR§872.3640<br>Endosseous dental implant | Similar classifications as per FDA interactions. |
| **Product Code** | QRQ | DZE | DZE | |
| **Intended Use** | The N1™ system Implant Site Preparation Tools are used to cut into the maxilla or mandible to create an osteotomy for endosseous dental implant placement. | Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant. | -- | The same intended use as the Primary Predicate expressed through a similar choice of words. |
| **Indications for Use** | The N1™ system Implant Site Preparation Tools are indicated to be used in the maxilla or mandible to prepare an osteotomy prior to placement of a Nobel Biocare N1™ TiUltra™ TCC implant. | 510k cleared Indications for Use:<br>NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.<br>NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability | 510(k) cleared Indications for Use:<br>Totally edentulous mandibles with a minimum height of 13mm and a minimum width of 6mm. Patient must be subject to dental treatment with endosseous implants. For use in a single stage procedure where the implants are immediately loaded. | Similar Indications for Use as the Primary Predicate expressed through a similar choice of words. |

| Substantial Equivalence OsseoShapers | | | | | |
|---|---|---|---|---|---|
| **Technological Characteristics** | | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive**<br>**(K142260 – Primary Predicate)** | **Reference Device**<br>**Branemark Novum**<br>**(K000018 – Reference #4)** | **Comparison** |
| | | | and appropriate occlusal loading for the selected technique.<br>NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.<br>NobelActive® 3.0 implants are indicated for single unit restorations only.<br>The Screw Tap used with the Implant System:<br>Screw Taps NobelActive are indicated for use in the maxilla or mandible to prepare an osteotomy in dense bone for placement of NobelActive® TiUnite™ Implants. | | |
| **Anatomical Site** | | Narrow Platform (NP)<br>Regular Platform (RP) | Narrow Platform (NP)<br>Regular Platform (RP) | -- | Same as Primary Predicate. |
| **Design** | **Maximum Diameter** | OsseoShaper 1 Nobel Biocare N1™: ø3.9 mm<br>OsseoShaper 2 Nobel Biocare N1™:ø4.4 mm | NP – ø3.54 mm<br>RP – ø4.3 mm | ø4.9 mm | The maximum diameter is within the range of the Primary Predicate and K000018 – Reference #4. The differences do not raise different questions of substantial equivalence, as demonstrated through heat generation testing. |
| | **Flute Insertion Length** | NP – 9.5, 11.5, 13.5 mm<br>RP – 7.5, 9.5, 11.5, 13.5 mm | NP – 8.2 mm<br>RP – 8.4 mm | 15.5 mm | The flute length range is similar to the range of the Primary Predicate and K000018 – Reference #4. The differences do not raise different questions of substantial equivalence, as demonstrated through heat generation testing. |
| | **Flute Design** | 3 flutes (helical) | 4 flutes (straight) | 3 flutes (straight) | The flute design is similar to K000018 – Reference #4. The differences do not raise different questions of substantial equivalence, as demonstrated through heat generation testing. |

| Substantial Equivalence OsseoShapers | | | | | |
|---|---|---|---|---|---|
| **Technological Characteristics** | | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive (K142260 – Primary Predicate)** | **Reference Device**<br>**Branemark Novum (K000018 – Reference #4)** | **Comparison** |
| | **Tip design** | 180° Flat | 180° Flat | 180° Flat | Same as the Primary Predicate and K000018 – Reference #4. |
| | **Material** | Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3) | Stainless Steel (ASTM F899) | Unalloyed Titanium (ASTM F67-95) | Similar to K000018 – Reference #4. The differences do not raise different questions of substantial equivalence, as demonstrated through heat generation testing and biocompatibility evaluation. |
| | **Surface Treatment** | OsseoShaper 1 Nobel Biocare N1™: None<br>OsseoShaper 2 Nobel Biocare N1™: Anodization | Screw Tap: DLC coating<br>NobelActive Implants: Anodization | -- | The differences in surface treatment do not raise different questions of substantial equivalence, as demonstrated through heat generation testing and biocompatibility evaluation. |
| | **Handpiece Connection** | ISO 1797 Type 1<br>ISO 17509 | ISO 1797 Type 1 | 2.4 mm square | The connection which is compatible with ISO 1797 Type 1 is shared with the Primary Predicate. The OsseoShapers offer an additional compatibility to ISO 17509. The differences do not raise different questions of substantial equivalence, as demonstrated through heat generation testing. |
| | **Markings** | Yes | Yes | -- | Same as Primary Predicate |
| **Drill Speed** | | Maximum 50 rpm | Maximum 25 rpm | -- | The drill speed is similar to the Primary Predicate. The differences do not raise different questions of substantial equivalence and is demonstrated through heat generation testing. |
| **Irrigation** | | No irrigation | No irrigation | No irrigation | Same as Primary Predicate. |
| **Duration of Use** | | Transient use during surgery | Transient use during surgery | Transient use during surgery | Same as Primary Predicate. |
| **Reusability** | | Single use | Reusable | Single use | Same as K000018 – Reference #4. The reusability differences of the OsseoShapers do not raise different questions of substantial equivalence as single use products have less associated sterility risks than reusable products and sterilization validation was performed. |

| **Substantial Equivalence OsseoShapers** | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive (K142260 – Primary Predicate)** | **Reference Device**<br>**Branemark Novum (K000018 – Reference #4)** | **Comparison** |
| **Packaging** | OsseoShaper 1 Nobel Biocare N1™: Co-packaged with corresponding implant in a polyethylene terephthalate glycol (PETG) Blister tray heat sealed with a Tyvek® lid (sterile barrier) inside a cardboard box (protective packaging) or single packed in sterile blister | Sterile blister | Sterile blister | Similar to the Primary Predicate. The differences do not raise different questions of substantial equivalence as demonstrated by packaging validation. |
| | OsseoShaper 1 Nobel Biocare N1 and OsseoShaper 2 Nobel Biocare N1™: Single packed in sterile blister | | | |
| **Sterilization** | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Same |

| Substantial Equivalence Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Comparison** |
| **Device** | | Multi-unit Abutment Xeal Nobel Biocare N1™ TCC | Multi-unit Abutment (MUA) Xeal™ | -- |
| **Pictorial Representation** | |  |  | -- |
| **Regulatory Number/ Device Classification Name** | | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | Same as Reference #1. |
| **Product Code** | | NHA | NHA | Same as Reference #1. |
| **Intended Use** | | Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Multi-unit Abutments TCC in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics is preferred. | MUA Xeal in combination with endosseous implants are intended for multiple unit reconstructions when screw retained prosthetics is preferred. | Same intended use as Reference #1and expressed with similar wording. |
| **Indications for Use** | | Multi-unit Abutment TCC is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. | The MUA Xeal is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. | Same as Reference #1. |
| **Design Features** | **Compatible Implants Platforms** | Narrow Platform (NP)<br>Regular Platform (RP) | 3.0 Platform<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP) | Same platforms are used within Reference #1. |
| | **Connection Interface** | Nobel Biocare Tri-oval Conical Connection (TCC) | Nobel Biocare Conical Connection (CC) | Similar to Reference #1. The differences do not raise different questions of substantial equivalence as demonstrated by the fatigue testing. |

| **Substantial Equivalence Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC** | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Comparison** |
| | **Abutment Height** | Straight: 1.5, 2.5, 3.5, 4.5 mm<br>Angulated 17°: 2.5, 3.5 mm<br>Angulated 30°: 3.5, 4.5 mm | Straight: 1.5, 2.5, 3.5, 4.5 mm<br>Angulated 17°: 2.5, 3.5 mm<br>Angulated 30°: 3.5, 4.5 mm | Same as Reference #1. |
| | **Abutment Width** | 4.8 mm | 4.8 mm | Same as Reference #1. |
| | **Abutment Angulation** | 0°, 17°, 30° | 0°, 17°, 30° | Same as Reference #1. |
| | **Material** | Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3) | Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3) | Same as Reference #1. |
| | **Surface Treatment** | Anodization | Anodization | Same as Reference #1. |
| | **Abutment Surface Topography** | Xeal – Single level surface<br>Sa <0.8 µm | Xeal – Single level surface<br>Sa <0.8 µm | Same as Reference #1. |
| | **Surface Preservation** | Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt | Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt | Same as Reference #1. |
| **Packaging** | | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier | Same as Reference #1. |
| **Sterilization** | | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Same as Reference #1. |

| Substantial Equivalence Universal Abutments | | | | |
|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| **Device** | Universal Abutment Nobel Biocare N1™ TCC<br>Nobel Biocare N1™ Base Xeal™ TCC Tri<br>Universal Abutment Nobel Biocare N1™ Base Tri<br>Universal Abutment Nobel Biocare N1™ Base Tri (Bridge) | On1 Base Xeal™<br>Multi-unit Abutment Xeal™ | Universal Base Conical Connection (CC) | -- |
| **Pictorial Representation** | Universal Abutment Nobel Biocare N1™ TCC<br>  | | Universal Base Conical Connection<br>  | -- |
| | Nobel Biocare N1™ Base Xeal™ TCC Tri<br>  | On1 Base Xeal<br>  | | |
| | Universal Abutment Nobel Biocare N1™ Base Tri<br>  | On1 Universal Abutment (indicated with the On1 Base Xeal)<br>  | | |

| **Substantial Equivalence Universal Abutments** | | | | |
|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| | Universal Abutment Nobel Biocare N1™ Base Tri (Bridge)<br>  | Multi-unit Abutment (MUA) Xeal [straight, 0°]<br>  | | |
| **Regulatory Number/ Device Classification Name** | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | Same as Reference #1. |
| **Product Code** | NHA | NHA | NHA | Same as Reference #1. |
| **Subsequent Product Code** | PNP | PNP | PNP | Same as Reference #1. |
| **Intended Use** | Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis. | The On1 Base Xeal™ is intended for use in the field of dentistry. It is intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function and esthetics.<br>The On1 Base Xeal™ on Nobel Biocare Conical Connection endosseous implants are indicated for single-unit cement retained restorations.<br>MUA Xeal™ in combination with endosseous implants are intended for multiple unit reconstructions when screw retained prosthetics is preferred. | The Universal Base Conical Connection are attached to Nobel Biocare dental implants and are intended to support a crown. | Same intended use as Reference #1 and expressed with similar wording. |

| **Substantial Equivalence Universal Abutments** | | | | |
|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| **Indication for Use** | Universal Abutment Nobel Biocare N1™ TCC<br>Universal abutments are indicated to support the placement of single unit, screw- retained prosthetic restorations in the maxilla or mandible.<br>The Universal Abutment consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment.<br>The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. | The On1 Base Xeal™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.<br>The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base Xeal, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment.<br>The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.<br>The MUA Xeal™ is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. | The Universal Base Conical Connection is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.<br>The Universal Base Conical Connection consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment.<br>The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. | Similar to Reference #1 and Reference #5. The Indications for Use are expressed through a similar of words. |
| | The Universal Abutment Nobel Biocare N1™ Base consist of three major parts. Specifically, the N1 Base Xeal, the Universal Abutment N1 Base, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. | | | |

| Substantial Equivalence Universal Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| | | Nobel Biocare N1™ Base Xeal™<br>The Nobel Biocare N1™ Base Xeal™ is indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function. It is indicated for single unit restorations and multiple unit restorations up to 6 units with less than 20° divergence to allow path of insertion.<br>Universal Abutment Nobel Biocare N1™ Base Tri<br>The Universal Abutment Nobel Biocare N1™ Base Tri is indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible.<br>Universal Abutment Nobel Biocare N1™ Base Tri Bridge<br>The Universal Abutment Nobel Biocare N1™ Base Tri Bridge is indicated to support the placement of multiple unit of up to 6 units, screw-retained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion. | | | |
| **Design Feature** | **Compatible Implants Platforms** | • Narrow Platform (NP)<br>• Regular Platform (RP) | • Narrow Platform (NP)<br>• Regular Platform (RP)<br>• Wide Platform (WP) | • Narrow Platform (NP)<br>• Regular Platform (RP)<br>• Wide Platform (WP) | The same platforms are used for Reference #1and Reference #5. |

| Substantial Equivalence Universal Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| **Connection Interface** | Universal Abutment Nobel Biocare N1 TCC | Nobel Biocare Tri-oval Conical Connection (TCC) | Nobel Biocare Internal Conical Connection | Nobel Biocare Internal Conical Connection | The UA N1 have similarly designed connection interfaces and the purpose of the connection interface is the same. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing. |
| | Nobel Biocare N1™ Base Xeal TCC Tri | Nobel Biocare Tri-oval Conical Connection (TCC) | | | |
| | Universal Abutment Nobel Biocare N1 Base Tri | Nobel Biocare N1 Base Connection | | | |
| | Universal Abutment Nobel Biocare N1 Base Tri (Bridge) | Nobel Biocare N1 Base Connection | | | |
| **Ti-base Material** | Titanium-aluminum-vanadium alloy (ASTM F136 and ISO 5832-3) | | Titanium-aluminum-vanadium alloy (ASTM F136 and ISO 5832-3) | Titanium-aluminum-vanadium alloy (ASTM F136 and ISO 5832-3) | Same as Reference #1. |
| **Mesostructure/Crown Material** | Zirconia<br>Nacera Pearl (K143071) Doceram Medical Ceramics GmbH | | On1 Base Xeal with the On1 Universal Abutment<br>Vita Enamic IS (K153645) Vita Zahnfabrik H. Rauter GmbH Co | Vita Enamic IS (K153645)<br>Vita Zahnfabrik H. Rauter GmbH Co | Same as Reference #1, materials that are cleared for mesostructure/crown fabrication. |

| **Substantial Equivalence Universal Abutments** | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| **Abutment Design** | Universal Abutment Nobel Biocare N1 TCC: 2-piece abutment, Abutment premanufactured, Single-unit<br>Nobel Biocare N1™ Base Xeal TCC Tri: 3-piece abutment. Abutment premanufactured, Single-unit and Multi-unit<br>Universal Abutment Nobel Biocare N1 Base Tri: 3-piece abutment. Abutment premanufactured, Single-unit<br>Universal Abutment Nobel Biocare N1 Base Tri (Bridge): 3-piece abutment. Abutment premanufactured, Multi-unit | On1 Base Xeal: 3-piece abutment. Abutment premanufactured, Single Unit<br>Multi-unit Abutment Xeal: 1-piece abutment, Abutment premanufactured, Multi-unit | 2-piece abutment<br>Abutment premanufactured<br>Single unit | Universal Abutment Nobel Biocare N1™ Base Tri, Universal Abutment Nobel Biocare N1™ Base Tri (Bridge), and Nobel Biocare N1™ Base Xeal™ TCC Tri are similar to Reference #1.<br>Universal Abutment Nobel Biocare N1™ TCC is the same as Reference #5.<br>The differences do not raise different questions of substantial equivalence, as demonstrated by fatigue testing. |
| **Abutment Fixation** | Abutment fixation with a screw. | Abutment fixation with a screw. | Abutment fixation with a screw. | Same as Reference #1. |
| **Maximum Abutment Angulation** | 20° | On1 Base Xeal with the On1 Universal Abutment<br>20° | 20° | Same as Reference #1. |
| **Wall Thickness Circular/ Margin (mesostructure)** | Circular: 0.5 mm<br>Margin: 0.35 mm | On1 Base Xeal with the On1 Universal Abutment<br>Circular: 0.8 mm min.<br>Margin: 0.275 mm min. | Circular: 0.8 mm min.<br>Margin: 0.275 mm min. | Similar to Reference #1. The differences do not raise different questions of substantial equivalence, as demonstrated by fatigue testing. |
| **Post Height Minimum** | 5.2 mm | On1 Base Xeal with the On1 Universal Abutment | 5.2 mm min. | Same as Reference #1. |

| **Substantial Equivalence Universal Abutments** | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| | | 5.2 mm min. | | |
| **Abutment Height** | Universal Abutment Nobel Biocare N1 TCC: 1.5, 3.0 mm<br>Nobel Biocare N1 Base Xeal TCC Tri: 1.75, 2.5, 3.5 mm<br>Universal Abutment Nobel Biocare N1 Base Tri: 4.5 mm<br>Universal Abutment Nobel Biocare N1 Base Tri (Bridge): 4.5 mm | On1 Base Xeal: 1.75, 2.5 mm<br>On1 Universal Abutment: 0.3, 1.25 mm<br>Multi-unit Abutment Xeal: 1.5, 2.5, 3.5, 4.5 mm | 1.5, 3.0 mm | Abutment heights are within the range of Reference #1. |
| **Abutment Width** | Universal Abutment Nobel Biocare N1 TCC: 4.5 mm<br>Nobel Biocare N1 Base Xeal TCC Tri: 4.2, 4.5 mm<br>Universal Abutment Nobel Biocare N1 Base Tri: 4.8, 5.0 mm<br>Universal Abutment Nobel Biocare N1 Base Tri (Bridge): 4.8, 5.0mm | On1 Base Xeal: 4.8, 5.3, 6.5 mm<br>Multi-unit Abutment Xeal: 4.8 mm | 4.775, 6.515 mm | Similar to Reference #1. The differences do not raise different questions of substantial equivalence, as demonstrated by fatigue testing. |

| Substantial Equivalence Universal Abutments | | | | | |
|---|---|---|---|---|---|
| | **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| | **Design Workflow** | • Scanner<br>Kavo LS3, 3Shape Trios or other scanners with equal or higher accuracy than 6.9 µm<br>• Design software<br>DTX Studio Design (K181932, where the implant libraries are automatically included in the software installer) or 3Shape Abutment Designer Software (K151455, where the implant libraries are obtained via the 3Shape server in the software). | On1 Base Xeal with the On1 Universal Abutment<br>• Scanner: Trios intra oral scanner by 3Shape A/S<br>• Design Software: 3Shape Abutment Designer Software (K151455, where the implant libraries are obtained via the 3Shape server in the software) | • Scanner Trios intra oral scanner by 3Shape A/S<br>• Design Software 3Shape Abutment Designer Software (K151455) | Similar to Reference #1 and Reference #5. The differences do not raise different questions of substantial equivalence, as demonstrated by manufacturing software verification and End-to-End (E2E) validation. |
| | **Manufacturing Workflow** | Milling unit<br>- Indicated for Zirconia milling<br>- Minimum 5 axis milling technology<br>- Minimum 30.000 rpm spindle speed | On1 Base Xeal with the On1 Universal Abutment<br>Milling unit<br>CORiTEC by imes-icore | Milling unit<br>CORiTEC by imes-icore | Similar to Reference #1and Reference #5. The differences do not raise different questions of substantial equivalence, as demonstrated by E2E validation. |
| | **Surface Treatment** | Anodization | Anodization | None | Same as Reference #1. |
| | **Surface Topography** | Universal Abutment Nobel Biocare N1 TCC: Ra[1] 1.6 µm (TCC Connection Sa[2]<0.6 µm)<br>Nobel Biocare N1 Base Xeal TCC Tri: Ra 0.8µm (TCC Connection Sa<0.6 µm)<br>Universal Abutment Nobel Biocare N1 Base Tri: Ra 0.8 µm | Sa <0.8 µm | Ra 0.8 | Similar to Reference #1and Reference #5. The differences do not raise questions of substantial equivalence, as demonstrated by fatigue testing and biocompatibility testing. |

[1] Profile Roughness (Ra)
[2] Area Roughness (Sa)

| **Substantial Equivalence Universal Abutments** | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| | Universal Abutment Nobel Biocare N1 Base Tri (Bridge) | Ra 0.8 µm | | | |
| **Surface Preservation** | Universal Abutment Nobel Biocare N1 TCC | None | Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt | None | Nobel Biocare N1™ Base Xeal™ TCC Tri is the same as Reference #1.<br>Universal Abutment Nobel Biocare N1™ TCC, Universal Abutment Nobel Biocare N1™ Base Tri and Universal Abutment Nobel Biocare N1™ Base Tri (Bridge) is the same as Reference #5.<br>The differences do not raise different questions of substantial equivalence, as demonstrated by biocompatibility testing and, packaging and sterilization validation. |
| | Nobel Biocare N1 Base Xeal TCC Tri | Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt | | | |
| | Universal Abutment Nobel Biocare N1 Base Tri | None | | | |
| | Universal Abutment Nobel Biocare N1 Base Tri (Bridge) | None | | | |
| **Packaging** | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | Same as Reference #1. |

| **Substantial Equivalence Universal Abutments** | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | | **Predicate Device**<br>**TiUltra Implants and Xeal Abutments (K202344 – Reference #1)** | **Reference Device**<br>**Universal Base Conical Connection (CC) (K200040 – Reference #5)** | **Comparison** |
| **Sterilization** | Universal Abutment Nobel Biocare N1 TCC | Non-sterile, end user sterilized | Gamma sterilization (SAL $10^{-6}$) | Non-sterile – end user sterilized | Similar to Reference #1and Reference #5.<br>The differences do not raise different questions of substantial equivalence, as demonstrated by cleaning and sterilization validation. |
| | Nobel Biocare N1 Base Xeal TCC Tri | Gamma Radiation (SAL $10^{-6}$) | | | |
| | Universal Abutment Nobel Biocare N1 Base Tri | Non-sterile, end user sterilized | | | |
| | Universal Abutment Nobel Biocare N1 Base Tri (Bridge) | Non-sterile, end user sterilized | | | |

| Substantial Equivalence Temporary Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| **Device Name** | Temporary Abutments | Healing Abutment Conical Connection WP<br>Temporary Snap Abutment Engaging Conical Connection WP | On1 Healing Cap<br>On1 Temporary Abutment Engaging | On1 IOS Healing Cap | -- |
| **Pictorial Representation** | Healing Abutment Nobel Biocare N1™ TCC<br>  | Healing Abutment Conical Connection WP<br>  | | | -- |
| | Temporary Abutment Nobel Biocare N1™ TCC<br>  | Temporary Snap Abutment Engaging Conical Connection WP<br>  | | | |
| | Healing Abutment Nobel Biocare N1™ Base Tri<br>  | | On1 Healing Cap<br>  | | |
| | Temporary Abutment Nobel Biocare N1™ Base Tri<br>  | | On1 Temporary Abutment Engaging<br>  | | |

| Substantial Equivalence Temporary Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | Temporary Abutment Nobel Biocare N1™ Base (Bridge)<br>  <br>IOS Healing Abutment Nobel Biocare N1™ Base Tri<br>  | | | On1 IOS Healing Cap:<br>  | |
| **Regulatory Number/ Device Classification Name** | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | Same as Reference #2. |
| **Product Code(s)** | NHA | NHA | NHA | NHA | Similar, all share the NHA product code. |
| **Intended Use** | Healing Abutment Nobel Biocare N1™ TCC:<br>Healing Abutments are intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.<br>Temporary Abutment Nobel Biocare N1™ TCC:<br>Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. | Definitive restorations<br>Provisional restorations | The On1™ devices are intended for use in the field of dentistry. They are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function and esthetics. The On1™ esthetic abutments in combination with the On1™ Base on Nobel Biocare Conical Connection endosseous implants are indicated for | The On1™ devices are intended for use in the field of dentistry. They are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function and esthetics. The On1™ esthetic abutments in combination with the On1™ Base on Nobel Biocare Conical Connection endosseous implants are indicated for | Same intended use as Reference #2, Reference #3, and Reference #6 and expressed through a similar choice of wording. |

| Substantial Equivalence Temporary Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | Healing Abutment Nobel Biocare N1™ Base Tri:<br>Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue.<br>Temporary Abutment Nobel Biocare N1™ Base and Temporary Abutment Nobel Biocare N1™ Base (Bridge):<br>Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.<br>IOS Healing Abutment Nobel Biocare N1™ Base:<br>Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue and transfer of position of a dental implant or implant abutment to a patient model | | single-unit cement retained restorations. | single-unit cement retained restorations. | |
| **Indications for Use** | Healing Abutment Nobel Biocare N1™ TCC:<br>Healing abutments are indicated for use with endosseous dental implants in the maxilla or mandible for supporting single tooth to full arch denture procedures. Healing abutments Nobel Biocare N1™ TCC are indicated for use for up to 180 days.<br>Temporary Abutment Nobel Biocare N1™ TCC:<br>Are indicated for use with single unit screw-retained temporary dental | Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or | The On1TM device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. | The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.<br>The On1™ Universal Abutment consists of three major parts. Specifically, the On1™ Base, the On1™ Universal Abutment, and the mesostructure components make up a | The Indications for Use are similar to Reference #2, Reference #3, and Reference #6 with the only difference being choice of similar wording. |

| Substantial Equivalence Temporary Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.<br><br><u>Healing Abutment Nobel Biocare N1™ Base Tri:</u><br>The Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days.<br><br><u>Temporary Abutment Nobel Biocare N1™ Base Tri:</u><br>The Temporary Abutment Nobel Biocare N1™ Base is indicated to support the placement of single unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days.<br><br><u>Temporary Abutment Nobel Biocare N1™ Base (Bridge):</u><br>The Temporary Abutment Nobel Biocare N1™ Base Bridge is indicated to support the placement of multiple unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days for implants with less than 20° overall divergences to allow path of insertion.<br><br><u>IOS Healing Abutment Nobel Biocare N1™ Base Tri:</u><br>The IOS Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for | multiple unit restorations in splinted or nonsplinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. | | multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. | |

<table>
<tr><th colspan="7">Substantial Equivalence Temporary Abutments</th></tr>
<tr><th>Technological characteristics</th><th colspan="2">Subject Device<br>N1™ TiUltra™ TCC Implant system</th><th colspan="2">Predicate Device<br>NobelActive Wide Platform (WP) – K133731 (Reference #2)</th><th colspan="2">Reference Device<br>On1 Concept– K161655 (Reference #3)</th><th>Reference Device<br>On1 Universal Abutment – K181869 (Reference #6)</th><th>Comparison</th></tr>
<tr><td></td><td colspan="2">supporting single unit and multiple unit procedures, for up to 180 days. In combination with intraoral scanner the IOS Healing Abutment can be used to confirm the location, position, and orientation of the Nobel Biocare N1™ Base Xeal™, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM.</td><td colspan="2"></td><td colspan="2"></td><td></td><td></td></tr>
<tr><td>Material</td><td colspan="2"><table><tr><td>Healing Abutment Nobel Biocare N1™ TCC</td><td rowspan="5">Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3)</td></tr><tr><td>Temporary Abutment Nobel Biocare N1™ TCC</td></tr><tr><td>Healing Abutment Nobel Biocare N1™ Base Tri</td></tr><tr><td>Temporary Abutment Nobel Biocare N1™ Base</td></tr><tr><td>Temporary Abutment Nobel Biocare N1™ Base (Bridge)</td></tr><tr><td>IOS Healing Abutment Nobel Biocare N1™ Base Tri</td><td>PEEK</td></tr></table></td><td colspan="2">Titanium-aluminum-vanadium alloy<br>(ASTM F136, ISO 5832-3)</td><td colspan="2">Titanium-aluminum-vanadium alloy<br>(ASTM F136, ISO 5832-3)</td><td>PEEK</td><td>The range of materials used for the Temporary Abutments, are the same as the materials used for Reference #2, Reference #3, and Reference #6. The differences do not raise different questions of substantial equivalence as demonstrated by biocompatibility testing.</td></tr>
<tr><td>Diameter</td><td colspan="2"><table><tr><td>Healing Abutment Nobel Biocare N1™ TCC</td><td>4.0 mm, 4.5 mm</td></tr><tr><td>Temporary Abutment Nobel Biocare N1™ TCC</td><td>3.4 mm, 3.7 mm</td></tr></table></td><td><table><tr><td>Healing Abutment CC WP</td><td>5.0 mm, 6.0 mm, 6.5 mm</td></tr><tr><td>Temporary Snap Abutment CC WP</td><td>3.4 mm</td></tr></table></td><td><table><tr><td>On1 Healing Cap</td><td>4.775 mm, 5.3 mm, 6.515 mm</td></tr><tr><td>On1 Temporary</td><td>3.4 mm, 3.7 mm, 4.0 mm</td></tr></table></td><td>4.775 mm, 5.3 mm</td><td>The range of the Temporary Abutment’s diameters falls within that of Reference #2.</td></tr>
</table>

| Substantial Equivalence Temporary Abutments | | | | | | |
|---|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | Healing Abutment Nobel Biocare N1™ Base Tri | 4.2 mm, 4.5 mm | | Abutment Engaging | | |
| | Temporary Abutment Nobel Biocare N1™ Base | 3.6 mm, 3.8 mm | | | | |
| | Temporary Abutment Nobel Biocare N1™ Base (Bridge) | 3.6 mm, 3.8 mm | | | | |
| | IOS Healing Abutment Nobel Biocare N1™ Base Tri | 4.2 mm, 4.5 mm | | | | |
| **Post Height** | Healing Abutment Nobel Biocare N1™ TCC | No post | Healing Abutment CC WP: No post<br>Temporary Snap Abutment CC WP: 4.0 mm | On1 Healing Cap: No post<br>On1 Temporary Abutment Engaging: 8.3, 9.0 mm | No post | The range of the Temporary Abutment's post height is similar to that of Reference #2 and Reference #3. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing on the connection. |
| | Temporary Abutment Nobel Biocare N1™ TCC | 10.5 mm | | | | |
| | Healing Abutment Nobel Biocare N1™ Base Tri | No post | | | | |
| | Temporary Abutment Nobel Biocare N1™ Base | 10.8 mm | | | | |
| | Temporary Abutment Nobel Biocare N1™ Base (Bridge) | 10.5 mm | | | | |
| | IOS Healing Abutment Nobel Biocare N1™ Base Tri | No post | | | | |
| **Gingival Height** | Healing Abutment Nobel Biocare N1™ TCC | 3.0 mm, 5.0 mm, 7.0 mm | Healing Abutment CC WP: 3.0 mm, 5.0 mm<br>Temporary Snap: 1.5 mm, 3.0 mm | On1 Healing Cap: 1.5 mm, 2.5 mm<br>On1 Temporary Abutment Engaging: -- | 4.5 mm, 6.0 mm | The range of the Temporary Abutment's gingival heights are similar to that of Reference #2 and Reference #6. The differences do not raise |
| | Temporary Abutment Nobel Biocare N1™ TCC | 1.5 mm, 3.0 mm | | | | |

| Substantial Equivalence Temporary Abutments | | | | |
|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | Healing Abutment Nobel Biocare N1™ Base Tri<br>Temporary Abutment Nobel Biocare N1™ Base<br>Temporary Abutment Nobel Biocare N1™ Base (Bridge)<br>IOS Healing Abutment Nobel Biocare N1™ Base Tri<br>-- | Abutment CC WP | | | different questions of substantial equivalence as demonstrated by fatigue testing on the connection. |
| **Angulation** | 0° | 0° | 0° | 0° | Same as Reference #2. |
| **Compatible Implant Platform** | - Narrow Platform (NP)<br>- Regulator Platform (RP) | Wide Platform (WP) | - Narrow Platform (NP)<br>- Regulator Platform (RP)<br>- Wide Platform (WP) | Narrow Platform (NP)<br>Regulator Platform (RP)<br>Wide Platform (WP) | The same platforms are used in Reference #3. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing on the connection. |
| **Connection Interface** | Healing Abutment Nobel Biocare N1™ TCC – Nobel Biocare Tri-oval Conical Connection<br>Temporary Abutment Nobel Biocare N1™ TCC – Nobel Biocare Tri-oval Conical Connection<br>Healing Abutment Nobel Biocare N1™ Base Tri – Nobel Biocare N1 Base Connection | Healing Abutment CC WP – Conical Connection<br>Temporary Snap Abutment CC WP – Hexagonal Snap into Conical Connection | On1 Healing Cap – On1 Prosthetic Connection<br>On1 Temporary Abutment Engaging – On1 Prosthetic Connection | On1 Prosthetic Connection | The connection interface has the same function as the connection of Reference #2. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing on the connection. |

| Substantial Equivalence Temporary Abutments | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | Temporary Abutment Nobel Biocare N1™ Base<br>Temporary Abutment Nobel Biocare N1™ Base (Bridge)<br>IOS Healing Abutment Nobel Biocare N1™ Base Tri | | | | |
| **Surface Treatment** | Healing Abutment Nobel Biocare N1™ TCC<br>Temporary Abutment Nobel Biocare N1™ TCC<br>Healing Abutment Nobel Biocare N1™ Base Tri<br>Temporary Abutment Nobel Biocare N1™ Base<br>Temporary Abutment Nobel Biocare N1™ Base (Bridge) — Anodization<br>IOS Healing Abutment Nobel Biocare N1™ Base Tri — None (machined) | Anodized | Anodized | None (machined) | The anodized surface treatment is the same as Reference #2. The machined surface is the same as Reference #6. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing on the connection and biocompatibility testing. |
| **Packaging** | Thermoformed polyethylene terephthalate glycol (PETG) blister | Thermoformed polyethylene terephthalate | Thermoformed polyethylene terephthalate | Thermoformed polyethylene terephthalate | Same as Reference #2. |

| **Substantial Equivalence Temporary Abutments** | | | | | |
|---|---|---|---|---|---|
| **Technological characteristics** | **Subject Device**<br>**N1™ TiUltra™ TCC Implant system** | **Predicate Device**<br>**NobelActive Wide Platform (WP) – K133731 (Reference #2)** | **Reference Device**<br>**On1 Concept– K161655 (Reference #3)** | **Reference Device**<br>**On1 Universal Abutment – K181869 (Reference #6)** | **Comparison** |
| | tray with medical paper lid forming a sterile barrier. | glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | |
| **Sterilization** | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Steam sterilized by end-user | Same as Reference #2. |

| Substantial Equivalence for the Screws of the N1 TiUltra TCC Implant system | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1 TiUltra TCC Implant system** | **Predicate Device**<br>**On1 Concept – K161655 (Reference #3)** | **Reference Device**<br>**Multi-unit Abutment Plus – K161416 (Reference #7)** | **Comparison** |
| **Device Name** | Clin Screw Multi-unit Abut Nobel Biocare N1™ TCC<br>Prosthetic Screw Nobel Biocare N1™ Base<br>Clinical Screw Nobel Biocare N1™ Base<br>Clinical Screw Nobel Biocare N1™ TCC | On1™ Clinical Screw<br>On1™ Prosthetic Screw | Clinical Screws MUA | -- |
| **Pictorial Representation** | Clin Screw Multi-unit Abut Nobel Biocare N1 TCC<br>  | | Clinical Screws MUA<br>  | -- |
| | Clinical Screw Nobel Biocare N1 Base<br>  | On1 Clinical Screw<br>  | | |
| | Clinical Screw Nobel Biocare N1 TCC<br>  | | | |
| | Prosthetic Screw Nobel Biocare N1 Base<br>  | On1 Prosthetic Screw<br>  | | |

| Substantial Equivalence for the Screws of the N1 TiUltra TCC Implant system | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1 TiUltra TCC Implant system** | **Predicate Device**<br>**On1 Concept – K161655 (Reference #3)** | **Reference Device**<br>**Multi-unit Abutment Plus – K161416 (Reference #7)** | **Comparison** |
| **Regulatory Number / Device Classification Name** | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | 21 CFR§872.3630<br>Endosseous dental implant abutment | Same as Reference #3. |
| **Product Code** | NHA | NHA | NHA | Same as Reference #3. |
| **Intended Use** | Prosthetic Screw Nobel Biocare N1™ Base and Clinical Screw Nobel Biocare N1™ Base:<br>The Clinical and Prosthetic Screw are intended to secure a dental abutment to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.<br>Clin Screw Multi-unit Abut Nobel Biocare N1™ TCC and Clinical Screw Nobel Biocare N1™ TCC:<br>The Clinical Screw is intended to secure a dental abutment to a dental implant in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. | The On1™ devices are intended for use in the field of dentistry. They are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function and esthetics.<br>The On1™ abutments in combination with the On1™ Base on Nobel Biocare Conical Connection endosseous implants are indicated for single-unit cement and screw retained restorations. | The Clinical Screw, Abutment Screw and Prosthetic Screw are intended to secure a dental abutment or framework to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. | Same intended use as Reference #3, expressed through similar wording. |
| **Indications for Use** | Prosthetic Screw Nobel Biocare N1™ Base and Clinical Screw Nobel Biocare N1™ Base:<br>The Clinical and Prosthetic Screw are to be directly connected to the dental implant, abutment or framework, intended for use as an aid in prosthetic rehabilitation.<br>Clin Screw Multi-unit Abut Nobel Biocare N1™ TCC and Clinical Screw Nobel Biocare N1™ TCC:<br>Clinical Screws are to be directly connected to the dental implant, | The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. | The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. | The Indications for Use are similar to Reference #3 with the only difference being the choice of similar wording. |

<table>
<tr><th colspan="5">Substantial Equivalence for the Screws of the N1 TiUltra TCC Implant system</th></tr>
<tr><th rowspan="2">Technological Characteristics</th><th>Subject Device</th><th>Predicate Device</th><th>Reference Device</th><th rowspan="2">Comparison</th></tr>
<tr><th>N1 TiUltra TCC Implant system</th><th>On1 Concept – K161655 (Reference #3)</th><th>Multi-unit Abutment Plus – K161416 (Reference #7)</th></tr>
<tr><td></td><td>abutment or framework, intended for use as an aid in prosthetic rehabilitation.</td><td></td><td></td><td></td></tr>
<tr><td>Material</td><td>Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3)</td><td>Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3)</td><td>Titanium-aluminum-vanadium alloy (ASTM F136, ISO 5832-3)</td><td>Same as Reference #3.</td></tr>
<tr><td>Shaft Diameter</td><td><table><tr><td>Prosthetic Screw Nobel Biocare N1 Base</td><td>1.25 mm, 1.3 mm</td></tr><tr><td>Clin Screw Multi-unit Abut Nobel Biocare N1 TCC</td><td rowspan="3">1.03 mm, 1.11 mm</td></tr><tr><td>Clinical Screw Nobel Biocare N1 Base</td></tr><tr><td>Clinical Screw Nobel Biocare N1 TCC</td></tr></table></td><td><table><tr><td>On1 Clinical Screw</td><td>1.185 mm, 1.475 mm</td></tr><tr><td>On1 Prosthetic Screw</td><td>1.175 mm</td></tr></table></td><td>1.17 mm, 1.5 mm</td><td>The range of the shaft diameters are similar to those of Reference #3 and Reference #7. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing.</td></tr>
<tr><td>Total Length</td><td><table><tr><td>Prosthetic Screw Nobel Biocare N1 Base</td><td>4.8 mm</td></tr><tr><td>Clin Screw Multi-unit Abut Nobel Biocare N1 TCC</td><td rowspan="3">6.8 mm, 6.9 mm, 9.7 mm, 10.7 mm, 11.7 mm, 12.7 mm</td></tr><tr><td>Clinical Screw Nobel Biocare N1 Base</td></tr><tr><td>Clinical Screw Nobel Biocare N1 TCC</td></tr></table></td><td><table><tr><td>On1 Clinical Screw</td><td>6.870 mm, 7.355 mm, 7.670 mm, 8.105 mm</td></tr><tr><td>On1 Prosthetic Screw</td><td>4.5 mm</td></tr></table></td><td>7.0 mm</td><td>The range of the total length are similar to those of Reference #3 and Reference #7. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing.</td></tr>
</table>

<table>
<tr><th colspan="5">Substantial Equivalence for the Screws of the N1 TiUltra TCC Implant system</th></tr>
<tr><th rowspan="2">Technological Characteristics</th><th colspan="2">Subject Device</th><th colspan="2">Predicate Device</th><th>Reference Device</th><th rowspan="2">Comparison</th></tr>
<tr><th colspan="2">N1 TiUltra TCC Implant system</th><th colspan="2">On1 Concept – K161655 (Reference #3)</th><th>Multi-unit Abutment Plus – K161416 (Reference #7)</th></tr>
<tr><td>Connection Interface</td><td colspan="2"><table><tr><td>Prosthetic Screw Nobel Biocare N1 Base</td><td>Nobel Biocare N1 Base Connection (N1 Base)</td></tr><tr><td>Clin Screw Multi-unit Abut Nobel Biocare N1 TCC</td><td>Nobel Biocare Tri-oval conical connection (TCC)</td></tr><tr><td>Clinical Screw Nobel Biocare N1 Base</td><td>N1 Base</td></tr><tr><td>Clinical Screw Nobel Biocare N1 TCC</td><td>TCC and N1 Base</td></tr></table></td><td colspan="2"><table><tr><td>On1 Clinical Screw</td><td>Nobel Biocare Internal Conical Connection (CC)</td></tr><tr><td>On1 Prosthetic Screw</td><td>On1 Base</td></tr></table></td><td>Nobel Biocare Internal Conical Connection (CC)</td><td>The connection interface shares the same purpose as those in Reference #3. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing.</td></tr>
<tr><td>Surface treatment</td><td colspan="2"><table><tr><td>Prosthetic Screw Nobel Biocare N1 Base</td><td rowspan="2">Anodized, DLC Coating</td></tr><tr><td>Clinical Screw Nobel Biocare N1 TCC</td></tr><tr><td>Clin Screw Multi-unit Abut Nobel Biocare N1 TCC</td><td rowspan="2">DLC Coating</td></tr><tr><td>Clinical Screw Nobel Biocare N1 Base</td></tr></table></td><td colspan="2"><table><tr><td>On1 Clinical Screw</td><td>Anodized, DLC Coating</td></tr><tr><td>On1 Prosthetic Screw</td><td>DLC Coating</td></tr></table></td><td>DLC Coating</td><td>Same surface treatments featured in Reference #3.</td></tr>
<tr><td>Abutment Compatibility</td><td colspan="2"><table><tr><td>Prosthetic Screw Nobel Biocare N1 Base</td><td>Single unit and Multi-unit</td></tr><tr><td>Clin Screw Multi-unit Abut Nobel Biocare N1 TCC</td><td>Multi-unit</td></tr></table></td><td colspan="2">Single unit</td><td>Multi-unit</td><td>Similar. The abutment compatibility is similar between Reference #3 and Reference #7. The differences do not raise different questions of substantial equivalence as demonstrated by fatigue testing.</td></tr>
</table>

| Substantial Equivalence for the Screws of the N1 TiUltra TCC Implant system | | | | |
|---|---|---|---|---|
| **Technological Characteristics** | **Subject Device**<br>**N1 TiUltra TCC Implant system** | **Predicate Device**<br>**On1 Concept – K161655 (Reference #3)** | **Reference Device**<br>**Multi-unit Abutment Plus – K161416 (Reference #7)** | **Comparison** |
| | Clinical Screw Nobel Biocare N1 Base: Single unit and Multi-unit<br>Clinical Screw Nobel Biocare N1 TCC: Single unit | | | |
| **Anatomical Site** | Narrow Platform (NP)<br>Regular Platform (RP) | Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP) | Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP) | Same, within the subset of Reference #3. |
| **Packaging** | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier. | Same as Reference #3. |
| **Sterilization** | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Gamma sterilization (SAL $10^{-6}$) | Same as Reference #3. |

**Summary of Non-Clinical Testing**

The following performance tests were submitted in this 510(k) to support substantial equivalence:

- **Sterilization validation** was conducted in accordance with:
    - ISO 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices;*
    - ISO 11137-2:2013, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose;*
    - ISO 11737-1:2018, *Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products; and*
    - ISO 11737-2:2009, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.*
- **Endotoxin testing** was conducted in accordance with:
    - USP 43-NF38:2020, *<161> Medical Devices—Bacterial Endotoxin and Pyrogen Tests;*
    - USP 43-NF38:2020, *<85> Bacterial Endotoxins Test; and*
    - ANSI/AAMI ST72:2011/(R)2016, *Bacterial endotoxins — Test methods, routine monitoring, and alternatives to batch testing.*
- **End user cleaning and sterilization validation** was conducted in accordance with:
    - ISO 17665- 1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;*
    - AAMI TIR12:2010, *Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers;*
    - AAMI / ANSI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities;*
    - ANSI/AAMI ST77:2013, *Containment devices for reusable medical device sterilization; and*
    - ISO 17664:2017, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices*.
- **Packaging performance testing** was conducted in accordance with:
    - ISO 11607-1:2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems;*
    - ASTM D4169:2016, *Standard Practice for Performance Testing of Shipping Containers and Systems;*

- ASTM D4332: 2014, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing;*
- ASTM F1886 / F1886M:2016, *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection;*
- ASTM F2096: 2011, *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test); and*
- ASTM F1980:2016, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

- **Biocompatibility testing** was conducted in accordance with:
  - ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process;*
  - ISO 10993-5:2009, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity;*
  - ISO 10993-12:2012, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials; and*
  - ISO 10993-18:2020, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*.
- **Mechanical testing** was conducted according to ISO 14801:2016, *Dentistry — Implants — Dynamic loading test for endosseous dental implants* and the FDA Guidance Document entitled, "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" (May 12, 2004).
- **Heat generation testing and insertion torque testing** was conducted with the N1 TiUltra TCC Implant system and the Primary Predicate. The comparative testing demonstrated the equivalence of the subject device to the predicate device.
- **An Animal Study** was conducted with the N1 TiUltra TCC Implant system and TiUltra Implants and Xeal Abutments (K202344) in a mini-pig model to evaluate the performance of the new drilling technique. The comparative study provided supportive data through: clinical observations, x-ray evaluation, micro-CT, and histology and histomorphometry to assess osseointegration at 13 ± 2 weeks. The devices exhibited the same representative osseointegration behavior at the assessed timepoint.
- **Mesostructure verification and validation** was completed on the Universal Abutments Nobel Biocare N1™ with the softwares and designated workflows. Software verification was provided for the subject abutment design library to demonstrate use with the softwares. Software verification demonstrated that the restrictions prevent design of the mesostructure component outside of design limitations. In addition, the abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.
- **MR conditional labeling** was leveraged from Nobel Biocare Dental Implant Systems Portfolio - MR Conditional – K212125 (Reference #8). The same type of testing was

conducted for the Subject Device and had acceptable outcomes to validate the labeling for MR Conditional.

The results of the non-clinical testing demonstrated that the N1 TiUltra TCC Implant system met the established performance specifications per intended use. The non-clinical testing also demonstrated that the N1 TiUltra TCC Implant system does not raise different questions of substantial equivalence when compared to the respective predicate devices.

**Summary of Clinical Testing**

To evaluate the long-term performance, osseointegration, and local effects of implantation that were unable to be fully addressed by the animal study, multiple sources of real-world evidence were provided to address concerns regarding the novel implant site preparation protocol (ISP) which employs fewer instruments and, in some steps, uses lower drill speeds and no irrigation in comparison to the ISP of the K142260 Primary Predicate, NobelActive. This body of clinical data addressed the necessary evaluation of critical clinical parameters for at least 12-months post-loading, including soft and hard tissues and bone loss, to support the success and safety of the Subject Device and its associated ISP drilling technique. These sources included a retrospective, multi-center, company-sponsored real-world study, supportive published literature, justification and detailed gap analysis of the representative test article, post-market surveillance data, clinical case studies, and clinical data gap analysis.

The primary clinical evidence was provided by the Nobel Biocare T-193 Evolution Study, a retrospective, multi-center, company-sponsored real-world study ("T-193 EVOLUTION Study"), conducted in Europe using a representative article, the Nobel Biocare N1 Concept System. The data provided in this study aligned with the recommendations of the FDA Guidance Document "*Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*." The study reported on 95 consecutive subjects, treated with 165 implants, out of which 145 implants had 12-month follow-up visit data after loading at study end, and included clinical and radiographic imaging data from the timepoint of surgery up to 12-months after loading. The primary endpoint was marginal bone level change (MBLC) of the Nobel Biocare N1 Concept System between the timepoint of implant loading to 12-months post loading. Secondary endpoints included implant survival and success rates at 12-months after loading, soft tissue healing parameters (i.e., bleeding index, plaque index, etc.) at 12-months after loading, and safety as recorded by adverse events (Device Deficiency, Adverse Device Effect, Serious Adverse Device Effect, and Unanticipated Serious Adverse Device Effect). Marginal bone level change (MBLC) from baseline (loading) to the 12-month follow-up visit, showed increased bone of 0.15 ± 0.84 mm (n=124 implants - for paired image analysis). Non-inferiority of marginal bone level change for Nobel Biocare N1 Concept System compared to historic data for NobelActive implant system (MacLean et al., 2016, and Aldahlawi,et al., 2018).[1,2] The primary endpoint of non-inferiority to published MBLC data of the Subject Device's Primary Predicate, NobelActive (K142260), was met with a statistical significance of $p<0.001$. The secondary endpoints for implant survival, implant success, tissue health, and safety events also resulted in clinically favorable outcomes. The successful clinical assessments and long-term results of clinical data evaluated also supported the biocompatibility of the Subject Devices related to the potential challenges associated with the novel ISP on local effects of implantation.

To address concerns relative to the use of a representative iteration of the Subject Device in the T-193 EVOLUTION Study, an assessment of the Subject Device's design and discussion of how the

Nobel Biocare N1 Concept System is representative of the Subject Device was provided. The design change assessment included details of the changes in design parameters (e.g., implant macro geometries), the reason for the change, and how the change may have impacted clinical performance demonstrated in the T-193 EVOLUTION Study's results. The impact of the changes on clinical performance was assessed by identifying biomechanical aspects of dental system designs which attribute to long-term performance, assessing each of these aspects thoroughly, and conducting a finite element analysis to assess implant loading distribution. Based on the individual and sum of the design changes, (i.e., including changes to the implant site preparation tools and protocol, the prosthetics, and the implants) as well as the use of a finite element analysis to model implant load distribution, the assessment concluded that the representative article (Nobel Biocare N1 Concept System) is the worst-case system and representative of the Subject Device.

Additional sources of real-world evidence provided to support the substantial equivalence of the Subject Device included the following:

- Post-Market Surveillance (PMS) data collected for the Subject Device as well as the associated restorative components from CE-mark accepting countries from May 2020 up to July 2021. Complaint rates associated with Nobel Biocare N1™ TiUltra™ TCC implants (Subject Device) were compared to the complaint rates of Primary Predicate NobelActive (K142260) during its first year of marketing (2008-2009) and were found to be lower.
- Supportive Published Literature was provided to add context to the T-193 EVOLUTION Study design and includes a discussion of how each publication was leveraged for the design of the T-193 EVOLUTION Study, including study endpoints, related indices, sample size calculation, calculation of marginal bone level change and implant survival rate. Several of the studies published historical data for NobelActive, the Subject Device's Primary Predicate (K142260).
- Clinical Data Gap Analysis - As all the clinical data presented is considered Real World Evidence, a gap analysis for each type of data was provided to demonstrate how the characteristics and evaluations of the real-world clinical evidence is relevant and reliable in order to demonstrate substantial equivalence of the Subject Device per the proposed intended use.

In summary, the totality of real-world evidence provided: the retrospective, multicenter clinical study, the post-market surveillance (PMS) data collected, supportive literature review provided to support the clinical study protocols and design, including studies published on the K142260 Primary Predicate, and the clinical data gap analysis was used to support the substantial equivalence of the Subject Device system, the N1 TiUltra TCC Implant System, to its Primary Predicate and identified reference devices.

[1] MacLean S, Hermans M, Villata L, et al. A retrospective multicenter case series evaluating a novel 3.0-mm expanding tapered body implant for the rehabilitation of missing incisors. Quintessence Int 2016;47(4):297-306

[2] Aldahlawi S, Demeter A, Irinakis T. The effect of implant placement torque on crestal bone remodeling after 1 year of loading. Clin Cosmet Investig Dent. 2018;10:203-9.

## Conclusions

The N1 TiUltra TCC Implant system was evaluated for substantial equivalence using standard and/or comparative testing. Based on a comparison of intended use, Indications for Use, material composition, technological characteristics, features, and performance (non-clinical and clinical) data the N1 TiUltra TCC Implant system is substantially equivalent to the predicate device.