September 16, 2022

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

Re: K220339
Trade/Device Name: Esthetic Abutments Nobel Biocare N1™
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 19, 2022
Received: August 19, 2022

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)*
K220339

Device Name
Esthetic Abutments Nobel Biocare N1™

Indications for Use *(Describe)*
Esthetic Abutment Nobel Biocare N1™ TCC:
The Esthetic Abutment Nobel Biocare N1™ TCC is a pre-manufactured component directly connected to an endosseous dental implant and is indicated for use as an aid in single unit prosthetic rehabilitation.

Esthetic Abutment Nobel Biocare N1™ Base:
The Esthetic Abutment Nobel Biocare N1™ Base is a pre-manufactured component connected to an endosseous dental implant and is indicated for use as an aid in single unit prosthetic rehabilitation.

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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510(k) Summary – K220339

Esthetic Abutments Nobel Biocare N1™

i. Submitter Information

Submitter:	Nobel Biocare AB Vastra Hamngatan 1 Goteborg 411 17 Sweden
Submitted By:	Nobel Biocare Services AG Balz-Zimmerman-Strasse 7 8302 Kloten Switzerland
Contact Person:	Bernice Jim, Ph.D
E-Mail:	regulatory.affairs@nobelbiocare.com
Telephone Number:	+41 79 855 00 73
Prepared By:	Heather Yates
Date Prepared	14 September 2022

ii. Device Name

Proprietary name:	Esthetic Abutments Nobel Biocare N1™
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Device Class:	II
Product Code:	NHA

iii. Predicate Devices

Primary Predicate Device

Propriety Name:	NobelActive Internal Connection Implant (K071370)
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Device Class:	Class II
Product Code:	DZE, NHA

Predicate Device #2

Propriety Name:	On1 Concept (K161655)
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Device Class:	Class II
Product Code:	NHA

Reference Device #1

Proprietary Name:	N1™ TiUltra™ TCC Implant system (N1™ system) (K211109)
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Implants
Classification Name:	Endosseous Dental Implant
Regulation Number:	21 CFR§872.3640
Regulatory Class:	II
Product Code:	DZE, NHA, PNP, QRQ

Reference Device #2

Proprietary Name:	Nobel Biocare Dental Implant Systems Portfolio – MR Conditional (K212125)
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Implants
Classification Name:	Endosseous Dental Implant and Abutment
Regulation Number:	21 CFR 872.3640, 21 CFR 872.3630, 21 CFR 872.4120
Regulatory Class:	II
Product Code:	DZE, NHA, PNP, DZI

iv. Device Description

Device Description

Esthetic Abutments Nobel Biocare N1™ are pre-manufactured dental implant abutments, intended for use as an aid in prosthetic rehabilitation. Esthetic Abutments Nobel Biocare N1™ are intended for use in the upper and/or lower jaw in combination with Nobel Biocare's Nobel Biocare N1™ implant system in order to restore patient esthetics and chewing function to partially or fully edentulous patients. The abutments are made from titanium vanadium alloy.

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 Esthetic Abutments Nobel Biocare N1™ because the submission covers several devices used together for a dental prosthetic procedure which has similar supportive data, and one FDA review division will be involved.
Esthetic Abutments Nobel Biocare N1™ is composed of two device lines.

- Esthetic Abutment Nobel Biocare N1™ TCC
- Esthetic Abutment Nobel Biocare N1™ Base

Table 5-1 – Accessory/Device List for Esthetic Abutment Nobel Biocare N1™ TCC

Device Line	Connection	Angulation	Platform	Post Height
Esthetic Abutment Nobel Biocare N1™ TCC	TCC	straight (0°), 15°	NP, RP	1.75 mm, 3mm
Esthetic Abutment Nobel Biocare N1™ Base	Base	straight (0°)	NP, RP	0.5mm

Esthetic Abutment Nobel Biocare N1™ TCC:

The Esthetic Abutment Nobel Biocare N1™ TCC are available in NP/RP platforms, with both straight and 15° angulation and 1.75 and 3mm heights available. The devices connect to a dental implant via a tri-oval conical connection (TCC), which is characterized by a trioval-shaped coronal zone and a round, moderately tapered body, and secured with a clinical screw. It is possible to modify the total height of the abutment in the dental laboratory. The 3mm abutments have a total height of 9.5 mm and can be modified to a minimum of 7.1 mm. The 1.75 mm abutments have a total height of 8mm and can be modified to a minimum of 5.6 mm.

Esthetic Abutment Nobel Biocare N1™ Base:

The Esthetic Abutment Nobel Biocare N1™ Base is available in two platforms (NP and RP). This device line is available as a straight abutment only, no angulated version is available. The devices connect to a dental implant by direct engagement and are secured with a prosthetic screw. It is possible to modify the total height of the abutment in the dental laboratory from 6.45 mm total height to a minimum of 4.5 mm.

v. Principle of Operation / Mechanism of Action

Esthetic Abutment Nobel Biocare N1™ TCC

Esthetic Abutment Nobel Biocare N1™ TCC can be directly connected to Nobel Biocare's Nobel Biocare N1™ TCC implants and and retained by a clinical screw, with which they are co-packed, using an Omnigrip Screwdriver. The Nobel Biocare's Nobel Biocare N1™ TCC implants and clinical screw were previously cleared in K211109.

Esthetic Abutment Nobel Biocare N1™ Base

The *Esthetic Abutment Nobel Biocare N1™ Base* can be connected to the Nobel Biocare N1™ Base Xeal™ (previously cleared, K211109) via a prosthetic screw, with which it is co-packed and secured using the Omnigrip. The Nobel Biocare N1™ Base Xeal™ is in turn connected to a Nobel Biocare N1™ TCC implant using a clinical screw.

The Esthetic Abutment Nobel Biocare N1™ Base has no direct interaction with either the implant, nor the clinical screw but they do form part of the final construct.

The N1™ Base Xeal™, prosthetic screw, Nobel Biocare N1™ TCC implants, clinical screw were previously cleared in K211109.

vi. Compatible Devices and accessories

The Esthetic Abutment Nobel Biocare N1™ TCC and Esthetic Abutment Nobel Biocare N1™ Base are intended to be used with the following previously cleared or exempt accessories/devices from Nobel Biocare below.

Esthetic Abutment Nobel Biocare N1™ TCC

The N1™ Esthetic Abutment Nobel Biocare N1™ TCC is intended to be used with the following exempt accessories/devices from Nobel Biocare.

Table 5-2 – Accessory/Device List for Esthetic Abutment Nobel Biocare N1™ TCC

Article No.	Product Name	Product Code	Regulation #	510(k) Clearance
300852	Screwdriver Machine Omnigrip Mini 20mm	NDP	872.3980	EXEMPT
300853	Screwdriver Machine Omnigrip Mini 28mm	NDP	872.3980	EXEMPT
300854	Screwdriver Machine Omnigrip Mini 36mm	NDP	872.3980	EXEMPT
300855	Screwdriver Manual Omnigrip Mini 20mm	NDP	872.3980	EXEMPT
300856	Screwdriver Manual Omnigrip Mini 36mm	NDP	872.3980	EXEMPT
300921	Abutment Retrieval Tool NB N1 TCC NP	NDP	872.3980	EXEMPT
300922	Abutment Retrieval Tool NB N1 TCC RP	NDP	872.3980	EXEMPT
300962	Implant Replica NB N1 TCC NP	NDP	872.3980	EXEMPT
300963	Implant Replica NB N1 TCC RP	NDP	872.3980	EXEMPT
300964	IOS Implant Replica NB N1 TCC NP	NDP	872.3980	EXEMPT
300965	IOS Implant Replica NB N1 TCC RP	NDP	872.3980	EXEMPT
300972	Lab Screw NB N1 TCC NP	NDP	872.3980	EXEMPT
300973	Lab Screw NB N1 TCC RP	NDP	872.3980	EXEMPT
300968	Clinical Screw Nobel Biocare N1™ TCC NP	NHA	872.3980	K211109
300969	Clinical Screw Nobel Biocare N1™ TCC RP	NHA	872.3980	K211109
300857	Nobel Biocare N1™ TiUltra™ TCC NP 3.5x9mm	DZE	872.3640	K211109
300858	Nobel Biocare N1™ TiUltra™ TCC NP 3.5x11mm	DZE	872.3640	K211109
300859	Nobel Biocare N1™ TiUltra™ TCC NP 3.5x13mm	DZE	872.3640	K211109
300860	Nobel Biocare N1™ TiUltra™ TCC RP 4.0x7mm	DZE	872.3640	K211109
300861	Nobel Biocare N1™ TiUltra™ TCC RP 4.0x9mm	DZE	872.3640	K211109
300862	Nobel Biocare N1™ TiUltra™ TCC RP 4.0x11mm	DZE	872.3640	K211109
300863	Nobel Biocare N1™ TiUltra™ TCC RP 4.0x13mm	DZE	872.3640	K211109

Esthetic Abutment Nobel Biocare N1™ Base

The N1™ Esthetic Abutment Nobel Biocare N1™ Base is intended to be used with the following exempt accessories/devices from Nobel Biocare.

Table 5-3 – Accessory/Device List for Esthetic Abutment Nobel Biocare N1™ Base

Article No.	Product Name	Product Code	Regulation #	510(k) Clearance
300852	Screwdriver Machine Omnigrip Mini 20mm	NDP	872.3980	EXEMPT
300853	Screwdriver Machine Omnigrip Mini 28mm	NDP	872.3980	EXEMPT
300854	Screwdriver Machine Omnigrip Mini 36mm	NDP	872.3980	EXEMPT
300855	Screwdriver Manual Omnigrip Mini 20mm	NDP	872.3980	EXEMPT
300856	Screwdriver Manual Omnigrip Mini 36mm	NDP	872.3980	EXEMPT
301021	Base Replica NB N1 Base Tri NP	NDP	872.3980	EXEMPT
301022	Base Replica NB N1 Base Tri RP	NDP	872.3980	EXEMPT
301024	IOS Base Replica NB N1 Base Tri NP	NDP	872.3980	EXEMPT
301025	IOS Base Replica NB N1 Base Tri RP	NDP	872.3980	EXEMPT
301033	Lab Screw NB N1 Base NP	NDP	872.3980	EXEMPT
301034	Lab Screw NB N1 Base RP	NDP	872.3980	EXEMPT
301029	Prosthetic Screw Nobel Biocare N1™ Base NP	NHA	872.3630	K211109
301030	Prosthetic Screw Nobel Biocare N1™ Base RP	NHA	872.3630	K211109
300982	Nobel Biocare N1™ Base Xeal™ TCC Tri NP 1.75mm	NHA	872.3630	K211109
300983	Nobel Biocare N1™ Base Xeal™ TCC Tri NP 2.5mm	NHA	872.3630	K211109
300984	Nobel Biocare N1™ Base Xeal™ TCC Tri NP 3.5mm	NHA	872.3630	K211109
300985	Nobel Biocare N1™ Base Xeal™ TCC Tri RP 1.75mm	NHA	872.3630	K211109
300986	Nobel Biocare N1™ Base Xeal™ TCC Tri RP 2.5mm	NHA	872.3630	K211109
300987	Nobel Biocare N1™ Base Xeal™ TCC Tri RP 3.5mm	NHA	872.3630	K211109

vii. Patient Contacting Components

Following the assessment set forth in ISO 10993-1:2018 Biological Evaluation of Medical Devices, Annex A, it was determined that the devices in scope of this submission do contain patient contacting components. The patient contacting components have direct patient contact components for a permanent duration of time (>30 days).

Table 5-4 – Patient Contacting Materials

Product Name Device Line	Material Description	Colorant
Esthetic Abutment Nobel Biocare N1™ TCC	Titanium-6 Aluminum-4 Vanadium alloy: 90% Ti, 6% Al, 4% V (ASTM F136 and ISO 5832-3) + Anodization	N/A
Esthetic Abutment Nobel Biocare N1™ Base	Titanium-6 Aluminum-4 Vanadium alloy: 90% Ti, 6% Al, 4% V (ASTM F136 and ISO 5832-3) + Anodization	N/A

viii. Indications for Use

Esthetic Abutment Nobel Biocare N1™ TCC:
The Esthetic Abutment Nobel Biocare N1 TCC is a pre-manufactured component directly connected to an endosseous dental implant and is indicated for use as an aid in single unit prosthetic rehabilitation.

Esthetic Abutment Nobel Biocare N1™ Base:
The Esthetic Abutment Nobel Biocare N1 Base is a pre-manufactured component connected to an endosseous dental implant and is indicated for use as an aid in single unit prosthetic rehabilitation.

ix. Substantial Equivalence - Device Line: Esthetic Abutments Nobel Biocare N1™ TCC

Details of the Similarities between the Subject and Primary Predicate Devices
The similarities between the Subject device line Esthetic Abutments Nobel Biocare N1™ TCC and the Primary Predicate Device as described in

Table **5-5** are as follows:

- The Intended Use/Principle of Operation of the Subject Device and the Primary Predicate Device are the same, with the only differences being the choice of similar wording. Both devices are used for supporting tooth replacements to restore chewing function. Furthermore, the Subject Device has the same Intended Use/Principle of operation as Reference Device #1.

- The Indications for Use of the Subject device and the Primary Predicate Device is the same and expressed through a similar choice of words. Both devices are pre-manufactured prosthetic components that are directly connected to endosseous dental implants. as an aid in prosthetic rehabilitation.

- The macro design and characteristics of the Subject device and the Primary Predicate Device are identical. Both devices are screw retained devices 1-piece abutments made from titanium vanadium alloy (Ti6Al4V ELI according to ASTM F136 and ISO 5832-3 with an anodization surface treatment.

- Both, the Subject Device, and the Primary Predicate Device are manufactured at the same Nobel Biocare centralized manufacturing facility utilizing the same manufacturing technology

- Both, the Subject Device, and the Primary Predicate Device connect directly to the implant and support both Narrow (NP) and Regular Platform (RP) and available in both straight and angulated profiles.

- The surface topography of the Subject Device and the Primary Predicate Device #1 are identical on the abutment surface. However, the connection area has the same surface topography as Reference Device #1. The differences do not raise new questions of substantial equivalence, as demonstrated by the performance testing.

- Both, the Subject Device, and the Primary Predicate Device are labelled MR Conditional. The Reference Device #2 (K212125) is included for reference to all MRI compatibility.

- The approach for non-clinical performance testing is the same for the Subject device and the Subject Device, and the Primary Predicate Device with the same fatigue limits for the two platforms. Testing was furthermore conducted to confirm that the technological differences between the devices do not raise different questions of substantial equivalence. The results of these tests support the Subject Device met the performance specifications and performed as intended.

Details of the differences between the Subject and Primary Predicate Devices:
There are no major differences however there are minor differences between the subject device and the Primary Predicate/Reference Device #1 such as:

- The Subject Device is connected to the implant via a tri-oval conical connection, whereas the Primary Predicate Device is connected via a conical connection.

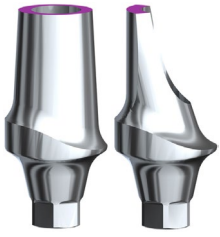
This difference does not affect the shared intended use, between the devices as demonstrated by non-clinical testing. The same connection (Trioval Conical Connection), with the same dimensions has been used for Reference Device #1.

- The device dimensions are different in the Subject Device and Primary Predicate Device. However, the maximum and minimum device dimensions are within the range of the Primary Predicate Device and Reference Device. Dynamic fatigue test for endosseous dental implants to the FDA Guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" was conducted in saline at 37 °C. The tests demonstrated the Subject Devices are substantially equivalent to the Primary Predicate Device and Reference Device #1.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the Esthetic Abutment Nobel Biocare N1™ TCC is deemed to be substantially equivalent to the Primary Predicate Device as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: Indications for Use, Technological Characteristics and Performance Data. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantial equivalent.

Table 5-5: Esthetic Abutment Nobel Biocare N1™ TCC comparison table

Descriptive Information	**Subject Device** Esthetic Abutments Nobel Biocare N1™ TCC	**Primary Predicate Device** NobelActive Internal Connection Implant – K071370 (limited to Esthetic Abutment Conical Connection)	**Reference Device #1** N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ TCC)	**Comparison**
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Nobel Biocare AB	Same
Pictorial Representation				N/A
Regulatory Classification				

Descriptive Information	**Subject Device** **Esthetic Abutments Nobel Biocare N1™ TCC**	**Primary Predicate Device** **NobelActive Internal Connection Implant – K071370 (limited to Esthetic Abutment Conical Connection)**	**Reference Device #1** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ TCC)**	**Comparison**
Regulation #	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same
Regulation Title	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant abutment	Same
Regulation Class	II	II	II	Same
Product Code	NHA	NHA	NHA	Same
Indications for Use/Intended Use				
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	The NobelActive Endosseous Dental Implants are intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using a single or 2-stage stage surgical procedure.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Same as Reference Device #1
Indications for Use	The Esthetic Abutment Nobel Biocare N1 TCC is a pre-manufactured component directly connected to an endosseous dental implant and is indicated for use as an aid in single unit prosthetic rehabilitation.	The 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. NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. NobelActive implants may be placed immediately and put into immediately function provided that initial stability requirements detailed in the manual are satisfied.	Universal abutments are indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxillae 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.	Same

Descriptive Information	**Subject Device** **Esthetic Abutments Nobel Biocare N1™ TCC**	**Primary Predicate Device** **NobelActive Internal Connection Implant – K071370 (limited to Esthetic Abutment Conical Connection)**	**Reference Device #1** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ TCC)**	**Comparison**
Technological Characteristics				
Compatible Implants Platforms	Narrow Platform (NP) Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Narrow Platform (NP) Regular Platform (RP)	Same
Connection Interface	Trioval Conical Connection (TCC)	Conical Connection (CC)	Trioval Conical Connection (TCC)	Same as Reference Device #1
Ti-base Material	Titanium Vanadium Alloy (ASTM F136 and ISO 5832-3)	Titanium Vanadium Alloy (ASTM F136 and ISO 5832-3)	Titanium Vanadium Alloy (ASTM F136 and ISO 5832-3)	Same
Angulation	Straight (0° angulation) and Angulated (15°)	Straight (0° angulation) and Angulated (15°)	Straight (0° angulation)	Same as Primary Predicate Device
Abutment Design	1-piece abutment Abutment pre-manufactured Single-unit	1-piece abutment Abutment pre-manufactured Single and Multi-unit	2-piece abutment Abutment pre-manufactured Single-unit	Same as Primary Predicate Device
Abutment Fixation	Abutment fixation with a screw.	Abutment fixation with a screw.	Abutment fixation with a screw.	Same
Esthetic Abutment Total Height (measured from implant level)	Straight/ Angulated: 1.75mm margin height: 8 mm total height (can be modified to minimum 5.6 mm) 3mm margin height: 9.5mm total height (can be modified to minimum 7.1mm)	Straight/ Angulated: 1.5mm margin height, 7.975 mm total height 3mm margin height, 9.475mm total height	1.5mm margin height, 5.55 mm total height 3mm margin height, 7.05mm total height	Substantial Equivalence demonstrated by fatigue testing.
Abutment modification	Yes	Yes	No	Same as Primary Predicate Device
Abutment Diameter	NP/RP: 4.4 mm (outer diameter of trioval profile)	NP: 4.2 mm x 4.88 mm	4.5 mm (outer diameter of trioval profile)	Substantial Equivalence demonstrated by fatigue testing.
Design Workflow	Traditional	Traditional	Scanner Kavo LS3, 3shape Trios or other scanners with equal or higher accuracy than 6.9 µm Design software	Same as Primary Predicate Device

Descriptive Information	**Subject Device** Esthetic Abutments Nobel Biocare N1™ TCC	**Primary Predicate Device** NobelActive Internal Connection Implant – K071370 (limited to Esthetic Abutment Conical Connection)	**Reference Device #1** N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ TCC)	**Comparison**
			DTX Studio Lab (the implant libraries are automatically included in the software installer) or 3Shape Dental Designer (the Implant Libraries are obtained via the 3Shape server in the software).	
Manufacturing Workflow	N/A	N/A	Milling unit - Indicated for Zirconia milling - Minimum5 axis milling technology - Minimum 30.000 rpm spindle speed	Same as Primary Predicate Device
Surface Treatment	Anodization	Anodization	Anodization	Same
Surface Topography	Ra 0.8 (TCC Connection Sa<0.6)	Ra 0.8	Ra 1.6 (TCC Connection Sa<0.6)	Abutment - Same as Same as Primary Predicate Device TCC Connection - Same as Reference Device #1
Surface Preservation	None	None	None	Same
Performance Testing				
Fatigue Testing	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Same
MRI Testing	MR Conditional	MR Conditional (as per K212125)	MR Conditional (as per K212125)	Same as Reference Device #2
Biocompat-ibility	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	Same

x.Substantial Equivalence - Device Line: Esthetic Abutment Nobel Biocare N1™ Base.

Details of the Similarities between the Subject and Predicate Device #2

The similarities between the Subject device line Esthetic Abutment Nobel Biocare N1™ Base and Predicate Device #2 as described in Table 5-6 are as follows:

- The Intended Use/Principle of Operation of the Subject Device and the Predicate Device #2 are the same, with the only differences being the choice of similar wording. Both devices are used for supporting tooth replacements to restore chewing function. Furthermore, the Subject Device has the same Intended Use/Principle of operation as Reference Device #1.

- The Indications for Use of the Subject device and the Predicate Device #2 is the same and expressed through a similar choice of words. Both devices are pre-manufactured prosthetic components that are connected to a Base level dental implant that are in turn connected to an endosseous dental implant.

- The macro design and characteristics of the Subject device and the Predicate Device #2 are identical. Both devices are 2-piece screw retained abutment devices made from titanium vanadium alloy (Ti6Al4V ELI according to ASTM F136 and ISO 5832-3 with an anodization surface treatment and the same surface topography.

- Both, the Subject Device, and the Predicate Device #2 are manufactured at the same Nobel Biocare centralized manufacturing facility utilizing the same manufacturing technology.

- Both, the Subject Device, and the Predicate Device #2 support both Narrow (NP) and Regular Platform (RP).

- Both, the Subject Device, and the Predicate Device #2 are labelled MR Conditional. The Reference Device #2 (Nobel Biocare Dental Implant Systems Portfolio – MR Conditional (K212125)) is included for reference to all MRI compatibility.

- The approach for non-clinical performance testing is the same for the Subject Device, and Predicate Device #2 with the same fatigue limits for the two platforms. Testing was furthermore conducted to confirm that the technological differences between the devices do not raise different questions of substantial equivalence. The results of these tests support the Subject Device met the performance specifications and performed as intended.

Details of the differences between Subject and Predicate Device #2:
There are no major differences however there are minor differences between the subject device and the Predicate Device #2/References Device #1 such as:

- Both the Subject and Predicate Device #2 connect directly to a base-level implant, which in turn connect to an endosseous dental implant. However, the base-level implant is specific to the implant system. This difference does not raise different questions of substantial equivalence. Fatigue testing was performed on the Subject Device and demonstrated comparable fatigue performance. Furthermore, the same connection (N1 Base, engaging), with the same dimensions has been used for the Subject Device and the Reference Device #1.

- The device dimensions are different in the Subject Device and Predicate Device #2. However, the maximum and minimum device dimensions are within the range of the Predicate Device #2 and Reference Device #1. Dynamic fatigue test for endosseous dental implants to the FDA Guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" was conducted in saline at 37 °C. The tests demonstrated the Subject Devices are substantially equivalent to the Predicate Device #2 and Reference Device #1.

Conclusion:
Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the Esthetic Abutment Nobel Biocare N1™ Base is deemed to be substantially equivalent to the Predicate Device #2 as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: Indications for Use, Technological Characteristics and Performance Data. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantial equivalent.

Table 5-6: Esthetic Abutment Nobel Biocare N1™ Base comparison table

Descriptive Information	**Subject Device** Esthetic Abutments Nobel Biocare N1™ Base	**Predicate Device #2** On1 Concept - K161655 (limited to On1 Esthetic Abutment Titanium)	**Reference Device #1** N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™Base Tri)	**Comparison**
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Nobel Biocare AB	Same
Pictorial Representation				N/A
Regulatory Classification				
Regulation #	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same
Regulation Title	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant abutment	Same
Regulation Class	II	II	II	Same
Product Code	NHA	NHA	NHA	Same
Indications for Use/Intended Use				
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	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™ abutments in combination with the On1™ Baseon Nobel Biocare Conical Connection endosseous implants are indicated for single-unit screw and	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Similar to Predicate Device #2 Same as Reference Device #1

Descriptive Information	**Subject Device** **Esthetic Abutments Nobel Biocare N1™ Base**	**Predicate Device #2** **On1 Concept - K161655** **(limited to On1 Esthetic Abutment Titanium)**	**Reference Device #1** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109** **(limited to Universal Abutment Nobel Biocare N1™Base Tri)**	**Comparison**
		cement retained restorations.		
Indications for Use	The Esthetic Abutment Nobel Biocare N1 Base is a pre-manufactured component connected to an endosseous dental implant and is indicated for use as an aid in single unit prosthetic rehabilitation	The On1™ device is a pre-manufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.	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.	Same
Technological Characteristics				
Compatible Implants Platforms	Narrow Platform (NP) Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Narrow Platform (NP) Regular Platform (RP)	Same
Connection Interface	N1 Base, engaging	On1, engaging	N1 Base, engaging	Same
Ti-base Material	MTA 005 Ti6Al4V ELI (ISO 5832)	MTA 005 Ti6Al4V ELI (ISO 5832)	MTA 005 Ti6Al4V ELI (ISO 5832)	Same
Angulation	Straight (0° angulation)	Straight (0° angulation)	Straight (0° angulation)	Same as Primary Predicate Device Same as Reference Device #1
Abutment Design	2-piece (base placed either at time of implant placement or with final abutment)	2-piece (base placed either at time of implant placement or with final abutment) Abutment shape fixed	3-piece abutment, pre-manufactured, Single-unit	Same as Predicate Device #2
Abutment Fixation	Abutment fixation with a screw.	Abutment fixation with a screw.	Abutment fixation with a screw.	Same

Descriptive Information	**Subject Device** **Esthetic Abutments Nobel Biocare N1™ Base**	**Predicate Device #2** **On1 Concept - K161655** **(limited to On1 Esthetic Abutment Titanium)**	**Reference Device #1** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109** **(limited to Universal Abutment Nobel Biocare N1™Base Tri)**	**Comparison**
Maximum Abutment Angulation	Straight	Straight	Straight	Same
Total height (measured from Base level)	6.45 mm (can be modified to 4.5 mm)	Total height On1 Esthetic Abutment 6.45mm	4.5 mm	Substantial Equivalence demonstrated by fatigue testing
Abutment modification	Yes	Yes	No	Same as Predicate Device #2
Margin height	0.5 mm	0.3 mm	0.45 mm	Substantial Equivalence demonstrated by fatigue testing
Abutment Diameter	NP: 4.6 mm RP: 4.8 mm	NP: 4.775 mm RP: 5.3 mm	NP: 4.8 mm RP: 5 mm	Substantial Equivalence demonstrated by fatigue testing
Design Workflow	Traditional	Traditional	• Scanner: Kavo LS3, 3Shape Trios or other scanners with equal or higher accuracy than 6.9 µm. • Design software: 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).	Same as Predicate Device #2

Descriptive Information	**Subject Device** Esthetic Abutments Nobel Biocare N1™ Base	**Predicate Device #2** On1 Concept - K161655 (limited to On1 Esthetic Abutment Titanium)	**Reference Device #1** N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™Base Tri)	**Comparison**
Manufacturing Workflow	N/A	N/A	Milling unit - Indicated for Zirconia milling - Minimum 5 axis milling technology - Minimum 30.000rpm spindle speed	Same as Predicate Device #2
Surface Treatment	Anodization	Anodization	Anodization	Same
Surface Topography	Ra 0.8µm (N1 Base Connection Ra=1.6 µm)	Ra 0.8µm (On1 Base Connection RA=1.6 µm)	Ra 0.8µm (N1 Base Connection Ra=1.6 µm)	Same
Performance Testing				
Fatigue Testing	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Same
MRI Testing	MR Conditional	MR Conditional (as per K212125)	MR Conditional (as per K212125)	Same as Reference Device #2
Biocompatibility	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	Same

xi. Performance Testing Data

Non-clinical testing was performed on the Subject device lines Esthetic Abutment Nobel Biocare N1™ TCC and Esthetic Abutment Nobel Biocare N1™ Base

- Dynamic loading testing performed according to ISO 14801 was conducted according to ISO 14801 and the FDA Guidance Document entitled, “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” (May 12, 2004).

- Magnetic Resonance compatibility testing according to ASTM F2052, ASTM F2213, ASTM F2119 and ASTM F2182
- Verification of biocompatibility of the final device in accordance with ISO 10993-1
- End user cleaning and sterilization validation in in accordance with ISO 17665-1 and AAMI TIR12,

Clinical Performance Data:
Clinical performance data is not required to establish substantial equivalence for the subject device.

xii. Conclusion

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the Esthetic Abutments Nobel Biocare N1™ is deemed to be substantially equivalent to the Predicate Devices.