July 29, 2022

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

Re: K220048
Trade/Device Name: NobelProcera® Zirconia N1™ Base
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 29, 2022
Received: June 30, 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)*
K220048

Device Name
NobelProcera® Zirconia N1™ Base

Indications for Use *(Describe)*

• NobelProcera® Zirconia Abutment/Implant Crown N1™ Base:
The NobelProcera® Zirconia Abutment/Implant Crown N1™ Base is a patient-matched CAD/CAM prosthetic component directly connected to an endosseous dental implant abutment with the Prosthetic Screw and is indicated for use as an aid in prosthetic rehabilitation.

• Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base:
The Prosthetic Screw is to be directly connected to the dental abutment or crown, indicated for use as an aid in 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 — K220048

NobelProcera® Zirconia N1™ Base

1. 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
Prepared By:	Manfred Müller
Date Prepared	29 July 2022

2. Device Name

Proprietary name:	NobelProcera® Zirconia N1™ Base
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

3. Predicate Device

Primary Predicate

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 No. 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 No. 2

Propriety Name:	NobelProcera Angulated Screw Channel Abutment Conical Connection (K132746)
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

4. Device Description

NobelProcera® Zirconia N1™ Base (premanufactured and patient matched prosthetic components) is composed of two subject device lines:

- NobelProcera® Zirconia Abutment / Implant Crown N1™ Base and
- Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base

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 NobelProcera® Zirconia N1™ Base (premanufactured and patient matched prosthetic components) 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.

The NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is a patient-matched specific CAD/CAM dental prosthesis which is connected to dental implants via a titanium base adapter (Nobel Biocare N1™ Base Xeal™ TCC Tri) and is intended for use as an aid in prosthetic rehabilitation to restore chewing function and esthetic appearance.
The NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is available as device in two restorative design solutions as described following:
a) The Abutment design is intended to mimic a prepared tooth which is then finalized with a restoration
b) The Implant Crown design incorporates part or all of the final restoration (i.e. Crown) into its design

The abutment / implant crowns are manufactured from zirconia (Yttria stabilized tetragonal zirconia according to ISO 13356) and are designed in a dental laboratory, hospital or dental practice by scanning, designing and ordering the restoration using dental CAD/CAM software and a Nobel Biocare/KaVo approved dental scanner.
The NobelProcera® Zirconia Abutment/Implant Crown N1™ Base can be modeled with conventional impression, using a model to be scanned with a desktop scanner or directly with an intra oral scan with a Nobel Biocare/Kavo approved scanner. The finished design is sent to Nobel Biocare manufacturing facility for industrial production. After production, the abutment / implant crown is sent to the laboratory for finishing.

NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is provided with the required Prosthetic Screw, the Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base which is a pre-manufactured dental prosthetic screw used to fasten the NobelProcera® Zirconia Abutment / Implant Crown N1™ Base to a titanium base adapter (Nobel Biocare N1™ Base Xeal™ TCC Tri). The Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base is made of titanium alloy according to ASTM F136 / ISO 5832-3.

The subject device lines are components of a two-piece abutment construct which consists of the Nobel Biocare N1™ Base Xeal™ TCC Tri (K211109) screw-retained using the Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base (subject device line) to the NobelProcera® Zirconia Abutment / Implant Crown N1™ (subject device line).

Principle of Operation / Mechanism of Action

The NobelProcera® Zirconia Abutment / Implant Crown N1™ Base are used for dental restoration purposes. The Zirconia abutments / implant crowns are mechanically connected to an endosseous implant via a titanium base adapter (Nobel Biocare N1™ Base Xeal™ TCC Tri) with the Subject Device line Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base to restore chewing function.

Patient Contacting Components

Following the assessment set forth in ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, Annex A, it was determined that the NobelProcera® Zirconia N1™ Base (premanufactured and patient matched prosthetic components) device lines do contain patient contacting materials. The device component's categorization and contact duration and identification of material or color additive are listed in Table 1.

Table 1: Patient Contacting Material List for NobelProcera® Zirconia N1™ Base (premanufactured and patient matched prosthetic components) device lines

Subject device lines	Device Category & Contact Duration	Material & Surface Treatment Description	Identification of Color Additive
NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	Permanent Implant Device (>30 days)	Nacera Pearl: Yttria-stabilized tetragonal zirconia (Y-TZP) (according to ISO 13356)	No Color Additive
Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base	Permanent Implant Device (>30 days)	Titanium vanadium alloy: 90% Ti, 6% Al, 4% V (according to ASTM F136 / ISO 5832-3) Diamond Like Carbon coating (DLC)	No Color Additive

Compatible Devices and accessories:

The NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is intended to be used with the following previously cleared or exempt accessories/devices from Nobel Biocare in Table 2 below. The subject device line Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base is included in the table as well for the purpose of comprehensiveness.

Table 2: NobelProcera® Zr Nobel Biocare N1™ Base Device/Accessory compatibility overview

Device / Accessory	Nobel Biocare N1™ Base Xeal™ TCC Tri (Article number)	Screw Driver Machine Omnigrip™ Mini (Article number)	Screw Driver Manual Omnigrip™ Mini (Article number)	Prosthetic screw Nobel Procera® Zr Nobel Biocare N1™ Base (Article number)	Lab Screw NobelProcera® Zr Nobel Biocare N1™Base (Article number)	Base Replica Nobel Biocare N1™ Base Tri (Article number)	IOS Base Replica Nobel Biocare N1™ Base Tri (Article number)
Pictorial Representation							
Article Numbers (Platform: NP)	300982, 300983; 300984	300852; 300853; 300854;	300855; 300856	301031	301035	301021	301024
Article Numbers (Platform: RP)	300985, 300986; 300987			301032	301036	301022	301025
Manufacturer	Nobel Biocare	Nobel Biocare	Nobel Biocare	Nobel Biocare	Nobel Biocare	Nobel Biocare	Nobel Biocare
Classification	Class II	Class I	Class I	Class II	Class II	Class I	Class I
Regulation Number	872.3630	872.3980	872.3980	872.3630	872.3980	872.3980	872.3980
Product Code	NHA, PNP	NDP	NDP	NHA	NDP	NDP	NDP
510(k)	K211109	Exempt	Exempt	n/a (Subject device line)	Exempt	Exempt	Exempt

5. Indication for Use

NobelProcera® Zirconia Abutment / Implant Crown N1™ Base:
The NobelProcera® Zirconia Abutment/Implant Crown N1™ Base is a patient-matched CAD/CAM prosthetic component directly connected to an endosseous dental implant abutment with the Prosthetic Screw and is indicated for use as an aid in prosthetic rehabilitation.

Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base:
The Prosthetic Screw is to be directly connected to the dental abutment or crown, indicated for use as an aid in prosthetic rehabilitation.

6. Substantial Equivalence

a) Substantial Equivalence NobelProcera® Zirconia Abutment / Implant Crown N1™ Base

Details of the Similarities Between the Subject and Primary Predicate
The similarities between the NobelProcera® Zirconia Abutment / Implant Crown N1™ Base (Subject Device) and the Primary Predicate, On1 Concept (K161655) as described in Table 3 below are as follows:

- The Intended Use and the Indications for Use is the same, expressed through a similar choice of words.
- The device design, the compatible Implant/Base platforms (NP/RP), the device connection/connector, the materials of the connector, the screw access and the device attachment method are identical for the Subject and Primary Predicate. Furthermore, both, the Subject and Primary Predicate are non-sterile, single-use devices. Additionally, the approach for biocompatibility and fatigue testing is the same for the Subject device and Primary Predicate.

Details of the Differences Between the Subject and Primary Predicate
There are no significant differences between the Subject and Primary Predicate but there are minor differences as follows:

- Both, the Subject device and the Primary Predicate utilizes a Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP) for the abutment / implant crown material according to ISO 13356. However, for the Subject device a pre-sintered Zirconia milling disk “Nacera Pearl” (FDA cleared Zirconia material cleared under K143071) has been used which is also utilized for the mesostructure as part of Reference No. 1 (Universal Abutment Nobel Biocare N1™ Base Tri and Nobel Biocare N1™ Base Xeal™ TCC Tri as part of N1™ TiUltra™ TCC Implant system; K211109)

- The design methods including the angulated screw channel dimensions and device dimensions, manufacturing and packaging are similar to Reference Device No. 2. Both devices are patient-matched devices with an individualized emergence profile and shape design. Both devices feature an angulated screw channel with the same screw channel angulation range (0° - 25°).
- The maximum device body angulation limits of the Subject device is similar to Reference Device No.1 and the difference is substantiated with fatigue testing.
- However, the Subject device feature two design options, i.e. abutment design and implant crown design, whereas the Primary Predicate device feature only an abutment design option.

These minor differences do not raise new concerns of substantial equivalence. The comparison below (Table 3) for the Subject device, Primary Predicate and Reference Devices demonstrate that the Subject device is substantially equivalent to the Primary Predicate with regards to their Indications for use, technology and performance specifications.
The subject device furthermore does not introduce a fundamentally new scientific technology, and nonclinical performance testing demonstrates that the device is substantially equivalent. The performance testing described in this submission supports the conclusion that the Subject device performs as well as the Primary Predicate device for its intended use.

Table 3: NobelProcera® Zirconia Abutment / Implant Crown N1™ Base comparison table

Device Characteristics	Subject device	Predicate device	Reference device	Reference device	Comparison
	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	**On1 Concept - K161655 (Primary Predicate)**	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri) (Reference Device No.1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746 (Reference Device No. 2)**	
Device	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	On1 Esthetic Abutment Zirconia On1 Base	Universal Abutment Nobel Biocare N1™ Base Tri Nobel Biocare N1™ Base Xeal™ TCC Tri	Nobel Procera Angulated Screw Channel Abutment Conical Connections	
Pictorial Representation	 Implant Crown  Abutment	 On1 Esthetic Abutment Zirconia  On1 Base	 Universal Abutment Nobel Biocare N1™ Base Tri (including mesostructure (right))  Nobel Biocare N1™ Base Xeal™ TCC Tri	 Nobel Procera Angulated Screw Channel Abutment Conical Connection with Adapter for Zirconia Abutment Conical Connection	
Regulatory Classification					
Regulatory Class Reg. Number / Classification name	Class II	Class II	Class II	Class II	Same as Primary Predicate

Device Characteristics	**Subject device**	**Predicate device**	**Reference device**	**Reference device**	Comparison
	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	**On1 Concept - K161655 (Primary Predicate)**	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri) (Reference Device No.1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746 (Reference Device No. 2)**	
	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	
Product Code	NHA	NHA	NHA, PNP	NHA	Same as Primary Predicate
Indications for Use/Intended Use					
Intended Use/ Principles of operation	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is a customized dental prosthetic device which is seated and attached directly to a dental implant abutment to facilitate restoration. NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is individually designed and manufactured to fulfill the clinical need of each patient. NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is made out of Zirconia and is delivered with a Prosthetic screw.	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 single-unit cement retained restorations.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Nobel Biocare's NobelProcera® ASC Abutment Zirconia is a customized dental abutment. The abutment is seated and attached directly to the endosseous dental implant and provides a platform for restoration. The NobelProcera® ASC Abutment Zirconia is individually designed and manufactured to fulfill the clinical need of each patient. The NobelProcera® ASC Abutment Zirconia is made out of Zirconia and is delivered with a titanium adapter and an Omnigrip™ clinical screw.	Same Indication for Use as Primary Predicate expressed through a similar choice of words

Device Characteristics	Subject device	Predicate device	Reference device	Reference device	Comparison
	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	**On1 Concept - K161655 (Primary Predicate)**	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri) (Reference Device No.1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746 (Reference Device No. 2)**	
Indication for Use	The NobelProcera® Zirconia Abutment / Implant Crown N1™ Base is a patient-matched CAD/CAM prosthetic component directly connected to an endosseous dental implant abutment with the Prosthetic Screw and is indicated for use as an aid 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.	n/a	The NobelProcera Angulated Screw Channel Abutment Conical Connection are premanufactured prosthetic components directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.	Same Indication for Use as Primary Predicate expressed through a similar choice of words
Technological Characteristics					
Device design	2-piece abutment construct which consists of the N1 Base Xeal TCC Tri (K211109) screw-retained using the Prosthetic Screw (subject device Table 4) to the NobelProcera® Zirconia Abutment / Implant Crown N1™ Base component (subject device)	2-piece abutment construct which consists of the On1 Base screw-retained using the Prosthetic Screw to the On1 Esthetic Abutment.	3-piece abutment construct which consists of the N1 Base Xeal TCC Tri (K211109) screw-retained using the Prosthetic Screw to the N1 Universal Base abutment and a cemented retained implant crown portion made of zirconium oxide.	2-piece abutment construct which consists of the Nobel Procera Angulated Screw Channel Abutment made of zirconium oxide screw-retained through the titanium Adapter for Zirconia Abutment Conical Connection using the Omnigrip Clinical Screw Conical Connection to the implant.	Similar to Primary Predicate
Compatible Implant/Base platform sizes	- Narrow Platform (NP) - Regular Platform (RP)	- Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)	- Narrow Platform (NP) - Regular Platform (RP)	- Narrow Platform (NP) - Regular Platform (RP)	Within the range of the Primary Predicate
Device connection / connector	The NobelProcera® Zirconia Abutment / Implant Crown N1™ Base component (subject device) is connected to the N1 Base Xeal TCC Tri (K211109) with the	The On1 Esthetic Abutment Device is connected to the On1 Base with the On1 Prosthetic Screw.	The mesostructure is cemented on top of the Universal Abutment Nobel Biocare N1™ Base and connected to Nobel Biocare N1™ Base Xeal™ TCC Tri with the	The Nobel Procera Angulated Screw Channel Abutment Conical Connection is connected to Adapter for Zirconia Abutment Conical Connection with the	Same concept as Primary Predicate

Device Characteristics	Subject device	Predicate device	Reference device	Reference device	Comparison
	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	**On1 Concept - K161655 (Primary Predicate)**	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri) (Reference Device No.1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746 (Reference Device No. 2)**	
	Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base (subject device in Table 4).		Prosthetic Screw Nobel Biocare N1™ Base.	Omnigrip Clinical Screw Conical Connection.	
Connector material	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832) NOTE: Nobel Biocare N1™ Base Xeal™ TCC Tri is not part of subject device and only included for illustration. This device has been cleared by K211109 (N1™ TiUltra™ TCC Implant system (N1™ system)), see Reference device No. 1	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832)	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832)	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832)	Same as Primary Predicate
Mesostructure/ Crown material	Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP) Nacera® Pearl Shaded 16+2 (K143071) by Doceram Medical Ceramics GmbH Blank manufacturer: Doceram Medical Ceramics GmbH 16+2 Shades (A1 to D2)	Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP)	Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP) Nacera® Pearl Shaded 16+2 (K143071) by Doceram Medical Ceramics GmbH Blank manufacturer: Doceram Medical Ceramics GmbH 16+2 Shades (A1 to D2)	Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP) Zirconia 4 shades (white-intense) by Nobel Biocare Blank manufacturer: Nobel Biocare	Similar to Primary Predicate Same as Reference Device No. 1

Device Characteristics	**Subject device** **NobelProcera® Zirconia Abutment / Implant Crown N1™ Base**	**Predicate device** **On1 Concept - K161655 (Primary Predicate)**	**Reference device** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109** **(limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri)** **(Reference Device No.1)**	**Reference device** **Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746** **(Reference Device No. 2)**	**Comparison**
	The chemical composition is according to ISO 13356 “Implants for surgery – Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP)	The chemical composition is according to ISO 13356 “Implants for surgery – Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP)	The chemical composition is according to ISO 13356 “Implants for surgery – Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP)	4 Zirconia shades (White to intense). The chemical composition is according to ISO 13356 “Implants for surgery – Ceramic material based on yttria-stabilized tetragonal zirconia (Y-TZP)	
Screw access	Platform specific ø of the screw hole and ASC NP: 2.9 mm RP: 3.1 mm	Platform specific ø of the screw hole NP/RP/WP: D2.44 mm No ASC feature	Platform specific ø of the screw hole NP: D2.5 mm RP: D2.7 mm No ASC feature	Platform specific ø of the screw hole and ASC NP: D2.5 mm RP: D2.65 mm	Similar to Primary Predicate
Emergence profile	Individualized	Standardized	Mesostructure: Individualized	Individualized	Same as Reference Device No. 1
Individual shape design	Individualized	Modifiable	Mesostructure: Individualized	Individualized	Same as Reference Device No. 1
Attachment method / Device Fixation	Screw retained	Screw retained	Mesostructure: Cemented on Universal Abutment Nobel Biocare N1™ Base Tri	Screw retained	Same as Primary Predicate
Angulated Screw channel	Yes	No	No	Yes	Same as Reference Device No. 2
Device dimensions	Maximum: • Diameter/width: 14.8 mm	Abutment Width at base • 4.8, 5.3 and 6.5 mm	Device dimensions of mesostructure:	Maximum (applicable for NP, RP): • Diameter: 20 mm	Similar to Reference devices

Device Characteristics	**Subject device** **NobelProcera® Zirconia Abutment / Implant Crown N1™ Base**	**Predicate device** **On1 Concept - K161655 (Primary Predicate)**	**Reference device** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109** **(limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri)** **(Reference Device No.1)**	**Reference device** **Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746** **(Reference Device No. 2)**	**Comparison**
	• Height: 16.8 mm Minimum: **NP:** • Min. Post height: 4.2 mm • Min. wall thickness: 0.4 mm **RP:** • Min. Post height: 4.2 mm • Min. wall thickness: 0.4 mm	Combined base and post height • 8.2 and 9.0 mm	Maximum (applicable for NP, RP): • Diameter: n /a • Height: 24.5 mm Minimum: **NP:** • Min. Post height: 5.2 mm • Min. wall thickness: 0.5 mm (circular) & 0.35 mm (margin) **RP:** • Min. Post height: 5.2 mm • Min. wall thickness: • 0.5 mm (circular) & 0.35 mm (margin)	• Height: 20 mm Minimum: **NP:** • Min. Post height: 3.3 mm • Min. wall thickness: 0.4mm **RP:** • Min. Post height: 3.1 mm • Min. wall thickness: 0.4 mm	
Screw channel angulation	between 0° to 25°	n/a	n/a	between 0° to 25°	Same as Reference Device No. 2

<table>
<tr><th rowspan="2">Device Characteristics</th><th><u>Subject device</u></th><th><u>Predicate device</u></th><th><u>Reference device</u></th><th><u>Reference device</u></th><th rowspan="2">Comparison</th></tr>
<tr><th>NobelProcera® Zirconia Abutment / Implant Crown N1™ Base</th><th>On1 Concept - K161655 (Primary Predicate)</th><th>N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri) (Reference Device No.1)</th><th>Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746 (Reference Device No. 2)</th></tr>
<tr><td>Maximum device body angulation</td><td>Angulation depending on margin height:
<table><tr><th>Margin height</th><th>Maximum angulation above margin height (soft tissue height) measured from top of the implant</th></tr><tr><td>< 4.4 mm</td><td>30°</td></tr><tr><td>5 mm</td><td>27°</td></tr><tr><td>6 mm</td><td>24°</td></tr><tr><td>7 mm</td><td>22°</td></tr><tr><td>8 mm</td><td>19°</td></tr></table></td><td>n/a</td><td>20°</td><td>n/a</td><td>Similar to Reference Device No.1, difference substantiated with fatigue testing</td></tr>
<tr><td colspan="6">Manufacturing, Packaging & Reusability</td></tr>
<tr><td>Design Method</td><td>Wax-up or CAD</td><td>n/a</td><td>CAD</td><td>Wax-up or CAD</td><td>Similar to Reference Device No. 1 and same as Reference Device No. 2</td></tr>
</table>

Device Characteristics	Subject device	Predicate device	Reference device	Reference device	Comparison
	NobelProcera® Zirconia Abutment / Implant Crown N1™ Base	**On1 Concept - K161655 (Primary Predicate)**	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri) (Reference Device No.1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746 (Reference Device No. 2)**	
Manufacturing	Industrialized manufacturing at NobelProcera manufacturing facility	Pre-manufactured	In-lab milling (dental laboratories)	Industrialized manufacturing at NobelProcera manufacturing facility	Same as Reference Device No. 2
Sterilization	Non-sterile	On1 Esthetic Abutment: Non-sterile On1 Base: Sterile (Gamma sterilization (SAL 10^{-6}))	Universal Abutment Nobel Biocare N1™ Base Tri: Non-sterile Nobel Biocare N1™ Base Xeal™ TCC Tri: Sterile (Gamma sterilization (SAL 10^{-6})) Mesostructure: Non-sterile	Non-sterile	Same as Primary Predicate
Reusability	Single use	Single use	Single use	Single use	Same as Primary Predicate
Packaging	Primary packaging: Transparent APET (amorphous polyethylene terephthalate) clamshell with grey polyester foam inlay inside. Secondary packaging: Cardboard shelf box	On1 Esthetic Abutment: Transparent PETG (polyethylene terephthalate glycol) blister sealed with medical paper lid. On1 Base: Transparent PETG (polyethylene terephthalate glycol) blister sealed with medical paper lid.	Universal Abutment Nobel Biocare N1™ Base Tri: Transparent PETG (polyethylene terephthalate glycol) blister sealed with medical paper lid. Nobel Biocare N1™ Base Xeal™ TCC Tri: Transparent PETG (polyethylene terephthalate glycol) blister sealed with medical paper lid.	Primary packaging: Transparent APET (amorphous polyethylene terephthalate) clamshell with grey polyester foam inlay inside. Secondary packaging: Cardboard shelf box	Same as Reference Device No. 2

Device Characteristics	**Subject device** **NobelProcera® Zirconia Abutment / Implant Crown N1™ Base**	**Predicate device** **On1 Concept - K161655 (Primary Predicate)**	**Reference device** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109** **(limited to Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri)** **(Reference Device No.1)**	**Reference device** **Nobel Procera Angulated Screw Channel Abutment Conical Connection - K132746** **(Reference Device No. 2)**	**Comparison**
Performance Testing					
Fatigue Performance	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Same as Primary Predicate
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Same as Primary Predicate

b) Substantial Equivalence Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base

Details of the Similarities Between the Subject and Reference Device No. 1

The similarities between the Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base and the Reference Device No. 1, Prosthetic Screw Nobel Biocare N1™ Base (device line of the N1™ TiUltra™ TCC Implant system (N1™ system)) as described in Table 4 below are as follows:

- The Intended Use statement and Indications for Use statement is the same and expressed through a similar choice of words.
- The Principle of operation, compatible Implant/Base platforms (NP/RP), device material, thread design and screw interfaces are the same for both, Subject device and the Reference Device No. 1.
- The approach for non-clinical performance testing is the same for the Subject device and Reference Device No. 1 .

Details of the Differences Between the Subject and Reference Device No. 1

There are no significant differences between the Subject and Reference Device No.1 but there are minor differences as follows:

- The Subject device and Reference Device No. 1 have different screw body dimensions including nominal total lengths
- Both devices, Subject device and Reference Device No. 1, are DLC (Diamond like carbon) coated, however, the screw head of the Subject Device is not anodized in comparison to the Reference Device No. 1.
- The Subject device is provided as non-sterile device to the user whereas the Reference Device No. 1 is provided as sterile device (Gamma sterilization) to the user. However, Reference Device No. 2 (Omnigrip Clinical Screw CC NP/RP, covered by Nobel Procera Angulated Screw Channel Abutment Conical Connection K1327467) is also provided as non-sterile device.
- The packaging of the Subject device and Reference Device No. 1 differs in utilized materials and overall packaging set-up.

However, these minor differences do not raise new concerns of substantial equivalence. The comparison below (Table 4) for the Subject device, Reference Device No. 1 and Reference device No. 2 demonstrates that the Subject device is substantially equivalent to the Reference Device No. 1 with regards to their Indications for use, technology, and performance specifications.

The subject device furthermore does not introduce a fundamentally new scientific technology, and nonclinical performance testing demonstrates that the device is substantially equivalent. The performance testing described in this submission supports the conclusion that the Subject device performs as well as the Reference Device No. 1 for its intended use.

Table 4: NobelProcera® Zirconia Abutment / Implant Crown N1™ Base comparison table

Device Characteristics	Subject Device	Reference device	Reference device	Comparison
	Prosthetic screw NobelProcera® Zr Nobel Biocare N1™ Base	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Prosthetic Screw Nobel Biocare N1™ Base) (Reference Device No. 1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K1327467 (limited to Omnigrip Clinical Screw CC NP/RP) (Reference Device No. 2)**	
Device	Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base	Prosthetic Screw Nobel Biocare N1™ Base	Omnigrip Clinical Screw CC NP/RP	
Pictorial Representation	 NP Screw RP Screw	 NP screw RP screw	 NP Screw  RP Screw	
Regulatory Classification				
Regulatory Class Reg. Number / Classification name	Class II 21 CFR 872.3630 Endosseous dental implant abutment	Class II 21 CFR 872.3630 Endosseous dental implant abutment	Class II 21 CFR 872.3630 Endosseous dental implant abutment	Same as Reference Device No. 1
Product Code	NHA	NHA	NHA	Same as Reference Device No. 1
Indications for Use/Intended Use				
Intended Use/ Principles of operation	The Prosthetic Screw is 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.	The Clinical and Prosthetic Screw are 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 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 as Reference Device No. 1

Device Characteristics	**Subject Device** **Prosthetic screw NobelProcera® Zr Nobel Biocare N1™ Base**	**Reference device** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Prosthetic Screw Nobel Biocare N1™ Base) (Reference Device No. 1)**	**Reference device** **Nobel Procera Angulated Screw Channel Abutment Conical Connection - K1327467 (limited to Omnigrip Clinical Screw CC NP/RP) (Reference Device No. 2)**	**Comparison**
Indications for Use	The Prosthetic Screw is to be directly connected to the dental abutment or crown, indicated for use as an aid in prosthetic rehabilitation	The Clinical and Prosthetic Screw are to be directly connected to the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.	N/A	Same Indication for Use as Reference Device No. 1 and expressed through a similar choice of words
Technological Characteristics				
Principle of operation (Attachment method)	The Prosthetic Screws NobelProcera® Zr NB N1™ Base are used to fix the NobelProcera® Zirconia N1™ Base Abutment / Implant Crown to the N1 Base abutment.	The Prosthetic Screw Nobel Biocare N1™ Base, act as connecting elements between a dental abutments and dental abutments. The mechanism of action is through a mechanical screw connection."	The Omnigrip clinical screws are used for securing the abutment to the endosseous implant.	Same as Reference Device No. 1
Compatible Implant/Base platform sizes	Narrow Platform (NP) Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Same as Reference Device No. 1
Device material	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832)	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832)	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136 / ISO 5832)	Same as Reference device No. 1
Surface material	PVD (DLC) surface treatment (SPE164652) No anodization	PVD (DLC) surface treatment (SPE164652) Anodization (Magenta for NP screw / Yellow for RP screw)	NP screw: N/A (machined surface, no PVD (DLC) coating) Blue anodization on screw head RP screw: PVD (DLC) surface treatment Blue anodization on screw head	Similar as Reference Device No. 1

Device Characteristics	**Subject Device** **Prosthetic screw NobelProcera® Zr Nobel Biocare N1™ Base**	**Reference device** **N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Prosthetic Screw Nobel Biocare N1™ Base) (Reference Device No. 1)**	**Reference device** **Nobel Procera Angulated Screw Channel Abutment Conical Connection - K1327467 (limited to Omnigrip Clinical Screw CC NP/RP) (Reference Device No. 2)**	**Comparison**
Screw body dimensions	Largest nominal diameter: NP: 2.68 mm RP: 2.88 mm Nominal total length: NP: 4.54 mm RP: 4.54 mm	Largest nominal diameter: NP: 2.34 mm RP: 2.54 mm Nominal total length: NP: 4.8 mm RP: 4.8 mm	Largest nominal diameter: NP: 2.375 mm RP: 2.525 mm Nominal total length: NP: 8.905 mm RP: 8.705 mm	Similar to Reference Device No. 1
Thread design	NP: M2x0.2 mm RP: M2.2x0.2 mm	NP: M2x0.2 mm RP: M2.2x0.2 mm	NP: M1.6 x 0.35 mm RP: M2 x 0.4 mm	Same as Reference Device No. 1
Screw Interface	Omnigrip Mini	Omnigrip Mini	Omnigrip	Same as Reference Device No. 1
Manufacturing, Packaging & Reusability				
Packaging set-up	Primary packaging: Transparent peelable bag made out of OPA-PE film. Secondary packaging: Cardboard jacket with transparent PET (polyethylene terephthalate) window.	Transparent PETG (polyethylene terephthalate glycol) blister sealed with medical paper lid.	Transparent PETG (polyethylene terephthalate glycol) blister sealed with medical paper lid.	Similar to Reference Device No. 1
Duration of use	Permanent Use	Permanent Use	Permanent Use	Same as Reference Device No. 1
Sterilization at supply	Non-sterile	Sterile (Gamma sterilization (SAL 10^{-6}))	Non-sterile	Same as Reference Device No. 2
Reusability	Single use	Single use	Single use	Same as Reference Device No. 1
Performance Testing				

Device Characteristics	**Subject Device**	**Reference device**	**Reference device**	Comparison
	Prosthetic screw NobelProcera® Zr Nobel Biocare N1™ Base	**N1™ TiUltra™ TCC Implant system (N1™ system) - K211109 (limited to Prosthetic Screw Nobel Biocare N1™ Base) (Reference Device No. 1)**	**Nobel Procera Angulated Screw Channel Abutment Conical Connection - K1327467 (limited to Omnigrip Clinical Screw CC NP/RP) (Reference Device No. 2)**	
Fatigue Performance	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Same as Reference Device No. 1
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Same as Reference Device No. 1

Performance Data:

Non-clinical testing was performed on the Subject device lines NobelProcera® Zirconia Abutment / Implant Crown N1™ Base and Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base

- Packaging system performance testing per ASTM D4169
- 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). Testing also includes evaluation of the removal torque to assess if any screw-loosening of the run-out samples happened during ISO 14801 cyclic loading.
- Wear assessment of the titanium components/zirconia contact area:
    - Assessment of all contacting surfaces of the subject device lines and the contacting surface of the Nobel Biocare N1™ Base Xeal™ TCC Tri using Light optical and SEM imaging following fatigue loading test according to ISO 14801 to demonstrate that the subject device lines present similar wear pattern in comparison with reference device systems (i.e. NobelProcera® Zirconia Implant Bridge (K202452) and NobelProcera® ASC Abutment CC (K132746))
    - In addition, real-world evidence on reference devices having DLC-coated prosthetic screw in contact with Zirconia abutments/restorations were reviewed. This real-world evidence according to the FDA Guidance Document entitled “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices” included the following:
        - Post-Market Surveillance (PMS) data on NPr ASC Ab Zirconia CC (K132746), collected from December 2013 up to January 2022. In this data set, the longest possible time a Zirconia abutment with a DLC-coated Omnigrip Clinical Screw CC has been in a patient was approximately 8.1 years. The complaint rates were low and well within Nobel Biocare’s predefined acceptance criteria and did not raise any concerns regarding the safety and effectiveness of utilizing dissimilar materials
        - Post-Market Surveillance (PMS) data for NobelProcera® Zr Implant Bridge (K202452), collected from May 2020 up to January 2022. In this data set, the longest possible time a Zirconia restoration has been in a patient was approximately 1.7 years. The complaint rates were low and well within Nobel Biocare’s predefined acceptance criteria and did not raise any concerns regarding the safety and effectiveness of utilizing dissimilar materials.

- Clinical Data on NPr ASC Ab Zirconia CC, obtained from 5 [1-5] clinical studies[1] reporting on 277 NPr ASC Ab Zirconia CC (K132746) with reported mean follow ups ranging between a mean of 0.6 and 3.6 years. The studies were included consecutively with no selection regarding study inclusion made besides the inclusion criterion that the NPr ASC Ab Zirconia CC had to be used in the study. The clinical endpoints comprised relevant parameters such as soft and hard tissue health, and adverse events. There were no reports of any wear debris stemming from the Zirconia restoration / DLC-coated screw. Nor were other adverse events or other clinical outcomes reported that would raise different questions of safety and effectiveness, for devices using dissimilar materials.
- 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 support safety and effectiveness for devices using dissimilar materials.

- 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

[1] [1] Greer, A.C., et al., Mechanical Complications Associated with Angled Screw Channel Restorations. Int J Prosthodont, 2017. 30(3): p. 258-259.
[2] Lv, X.-L., et al., Clinical, radiographic, and immunological evaluation of angulated screw-retained and cemented single-implant crowns in the esthetic region: A 1-year randomized controlled clinical trial. Clinical Implant Dentistry and Related Research, 2021. 23(5): p. 692-702.
[3] Friberg, B. and M. Ahmadzai, A prospective study on single tooth reconstructions using parallel walled implants with internal connection (NobelParallel CC) and abutments with angulated screw channels (ASC). Clin Implant Dent Relat Res, 2019. 21(2): p. 226-231.
[4] Sanz-Martin, I., et al., Soft tissue augmentation at immediate implants using a novel xenogeneic collagen matrix in conjunction with immediate provisional restorations: A prospective case series. Clin Implant Dent Relat Res, 2019. 21(1): p. 145-153.
[5] Fabbri, G., et al., Factors associated with prosthetic complications with individualized abutments: Real-world data [EAO-660], in European Association for Osseointegration Congress. accepted 2022: Geneva.

7. Conclusion

NobelProcera® Zirconia N1™ Base (premanufactured and patient matched prosthetic components) consisting of the two subject device lines (NobelProcera® Zirconia Abutment / Implant Crown N1™ Base and Prosthetic Screw NobelProcera® Zr Nobel Biocare N1™ Base) are substantially equivalent to the Primary Predicate (On1 Concept – K161655) and Reference Devices (Universal Abutment Nobel Biocare N1™ Base Tri & Nobel Biocare N1™ Base Xeal™ TCC Tri as well as Prosthetic Screw Nobel Biocare N1™ Base as part of N1™ TiUltra™ TCC Implant system (N1™ system) - K211109)).