December 3, 2020

Nobel Biocare AB
Bernice Jim
Regulatory Affairs Manager
Vastra Hamngatan 1
Goteborg Gotlands Lan, 411 17
SWEDEN

Re: K202452
Trade/Device Name: NobelProcera Zirconia Implant Bridge
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 3, 2020
Received: November 4, 2020

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 Steen
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202452

Device Name

NobelProcera Zirconia Implant Bridge

Indications for Use *(Describe)*

The NobelProcera® Zirconia Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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 – K202452

005-01 Submitter Information

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December 3, 2020

005-02 Device

Proprietary name:	NobelProcera Zirconia Implant Bridge
Manufacturer:	Nobel Biocare Services AG
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Product Code:	NHA

005-03 Predicate Device

Predicate Device

Proprietary Name:	NobelProcera HT ML FCZ Implant Bridge and Framework (K160158)
Manufacturer:	Nobel Biocare Services AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Product Code:	NHA

Reference Device #1

Proprietary Name:	Nacera Pearl (K143071)
Manufacturer:	DOCERAM Medical Ceramics GmbH
Common Name:	Porcelain Powder Blanks
Classification Name:	Porcelain Powder for Clinical Use
Regulation Number:	21 CFR 872.6660
Regulatory Class:	II
Product Code:	EIH

Reference Device #2

Proprietary Name:	NobelProcera Implant Bridge Zirconia (K091907)
Manufacturer:	Nobel Biocare Services AG
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Regulatory Class:	II
Product Code:	NHA

Reference Device #3

Proprietary Name:	NobelZygoma 0° (K161598)
Manufacturer:	Nobel Biocare Services AG
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3640
Regulatory Class:	II
Product Code:	DZE, NHA

Reference Device #4

Proprietary Name:	Elos Accurate® Customized Abutment (K171799)
Manufacturer:	Elos Medtech Pinol A/S
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Regulatory Class:	II
Product Code:	NHA

005-04 Device Description

NobelProcera Zirconia Implant Bridges (Dental Bridges) are patient-specific, dental implant supported, screw-retained dental implant bridges which are connected to compatible Nobel Biocare root-form endosseous dental implants or Multi-unit abutments and are intended to restore chewing function in partially and fully edentulous patients. The Dental Bridge is available as either a Framework requiring veneering in a dental lab or as a Full Contour design requiring minimum laboratory processing.

NobelProcera Zirconia Implant Bridges are made from 'Nacera Pearl' (yttria-stabilized tetragonal zirconia), Reference Device #1, K143071. The Dental Bridges 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 finished design is sent to Nobel Biocare manufacturing facility for industrial production. After production, the Dental Bridge is sent to the laboratory for finishing.

NobelProcera Zirconia Implant Bridges are available for use with Nobel Biocare's root-form endosseous dental implants (Dental Implants) having Internal Conical Connection (CC), External Hex Connection, Internal Tri-Channel Connection and Nobel Biocare's Multi-unit Abutment Connections (for MUA and MUA Plus). One Dental Bridge can feature connections to 2 to 10 Dental Implants.

All NobelProcera Zirconia Implant Bridges are provided with the required clinical and/or Prosthetic Screw: The clinical screw connects the Dental Bridge with the Dental Implant. The Prosthetic Screw connect the Dental Bridge with a Multi-unit Abutment.

Dental Bridge connections on the Internal Conical Connection Dental Implant require use of Clinical Metal Adapters. Clinical Metal Adapters are provided with the Dental Bridge. No adapter is needed for the external hex, internal tri-channel, or Multi-unit abutment connections.

Principle of Operation / Mechanism of Action

The NobelProcera Zirconia Implant Bridges (Dental Bridges) are used for dental restoration purposes. The Dental Bridge can mechanically be connected to endosseous dental implants directly with clinical screws (Implant Level) or it can be connected via Multi-unit Abutments (MUA Level) with Prosthetic Screws to restore chewing function.

Device/Accessory List

The NobelProcera Zirconia Implant Bridge is provided with the required clinical and/or prosthetic screws. Bridges intended to be connected to an implant with Internal Conical Connection are shipped with the Clinical Metal Adapter.

The NobelProcera Zirconia Implant Bridge is intended to be used with the following previously cleared or exempt accessories/devices from Nobel Biocare. The Subject device component 'Prosthetics Screws' are included in the Table 005-1 as well for the purpose of comprehensiveness.

Table 005-1: NobelProcera Zirconia Implant Bridge compatibilities overview

Compatible Implant /Abutment Platform	Platform	Clinical Metal Adapter (Article number)	Clinical Screw (Article number)	Prosthetic Screws (Article number)
Compatible Abutment Platform Sizes				
Multi-unit Multi-unit Plus	NP/RP/WP except Multi-unit External Hex WP	N/A	N/A	301203 (Subject Device)
Multi-unit Multi-unit Plus	External Hex WP		N/A	301200 (Subject Device)
Compatible Implant Connection and Platform Sizes				
Conical connection	NP	38483 (K160158)	37367 (K132746)	N/A
	RP	38484 (K160158)	37606 (K132746)	N/A
	WP	38525 (K160158)		N/A
Tri-channel connection	NP	N/A	28837 (K091904)	N/A
	RP		28816 (K091904)	N/A
	WP			N/A
	6.0			N/A
External Hex	NP	N/A	31171 (K905434)	N/A
	RP		28815 (K091904)	N/A
	WP		28844 (K091904)	N/A

005-05 Indications for use

The NobelProcera® Zirconia Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

005-06 Substantial Equivalence Discussion

The Subject Device 'NobelProcera Zirconia Implant Bridge' from Nobel Biocare functions in a manner similar to and is intended for the same indications for use as the Predicate Device 'NobelProcera HT ML FCZ Implant Bridge and Framework' (K160158) marketed by Nobel Biocare. There are numerous identical design and technological characteristics such as indications for use, compatible dental implants connections, device material, bridge design (restoration type), bridge design with arc length and angulated screw channel, angulated screw channel angulation between 0° to 25°, and manufacturing method.

However, there are different technological characteristics: The Subject Device 'NobelProcera Zirconia Implant Bridge' is manufactured from a pre-sintered milling disk 'Nacera Pearl' (Reference Device #1, K143071) which allows for a maximum number of 10 implants as opposed to the Predicate which allows for 14 implants. The Dental Bridge extends the MUA level to allow connection with the Multi-unit Abutment Plus (MUA Plus) (K161416) and has an ASC feature for the MUA and MUA Plus using the Prosthetic Screw. In addition, the Prosthetic Screw MUA Omnigrip Mini features a DLC coating which is also featured in the abutment screws of the reference devices NobelZygoma 0° (Reference Device #3, K161598) and the Elos Accurate® Customized Abutment (Reference Device #4, K171799).

These different technological characteristics do not raise new concerns of substantial equivalence. The comparison table below (Table 005-2) for the NobelProcera Zirconia Implant Bridge (Subject device) to the NobelProcera HT ML FCZ Implant Bridge and Framework (Predicate Device) are substantially equivalent in terms of indication for use, technology and performance specifications as the few differences between the Subject Device and the Predicate Device do not impact substantial equivalence. The performance testing results provided in this submission supports that the Subject Device performs as well as the Predicate Devices for its intended use.

Table 005-2: Substantial Equivalence Table

Device characteristics	**Subject Device**		**Predicate Device: K160158**	**Reference Device #1: K143071**	**Reference Device #2: K091907**	**Reference Device #3: K161598**	**Reference Device #4: K171799**
	NobelProcera Zirconia Implant Bridge		NobelProcera HT ML FCZ Implant Bridge and Framework	Nacera Pearl	NobelProcera Implant Bridge Zirconia	NobelZygoma 0°	Elos Accurate® Customized Abutment
Pictorial Representation	 Dental Bridge (here shown with two Clinical Metal Adapters)		 FCZ Implant Bridge and Framework	NA	NA	N/A	NA
	 Prosthetic Screw	 Clinical Metal Adapter	 Clinical Metal Adapter				
Regulatory Classification							
Regulatory Class Reg. Number Classification Name Product code	Class II 21 CFR 872.3630 Endosseous Dental Implant Abutment NHA		Class II 21 CFR 872.3630 Endosseous Dental Implant Abutment NHA	Class II 21 CFR 872.6660 Porcelain Powder for Clinical Use EIH	Class II 21 CFR 872.3630 Endosseous Dental Implant Abutment NHA	Class II 21 CHR 872.3640 Endosseous Dental Implant DZE, NHA	Class II 21 CFR 872.3630 Endosseous Dental Implant Abutment NHA

Indications for Use/Intended Use						
Indication for Use	The NobelProcera Zirconia Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	The NobelProcera HT ML FCZ (full contour zirconia) and framework Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	Nacera Pearl blanks are indicated for the fabrication of single crowns and bridgework: - fully anatomical single crowns and bridgework (FCZ) - Partially veneered or fully veneered crowns and bridges - Inlays, onlays, and Maryland bridges - Primary telescopic crowns for anterior and posterior applications	The NobelProcera Implant Bridge Zirconia is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	NobelZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw. The Elos Accurate® Customized Abutments are compatible with the following implant systems: Nobel Biocare/Branemark RP, 3.75 & 4mm Nobel Biocare/Branemark NP, 3.3mm Nobel Biocare/Branemark WP, 5mm All digitally designed Elos Accurate® Customized Abutments are intended to be manufactured at an Elos Medtech approved milling facility.
Intended use	The NobelProcera® Zirconia Implant Bridges are customized dental implant bridges. The implant Bridge attaches directly to the endosseous dental implants and/or onto Nobel Biocare's Multi-unit Abutments with prosthetic screws and provides a platform for restoration. The NobelProcera® Zirconia Implant Bridges are designed and made individually to fit the individual requirements for the patient. NobelProcera® Zirconia Implant Bridges are indicated for a bridge span of 2 to up 14 units, on 2 up to 10 implants.	The NobelProcera HT ML FCZ Implant Bridge and Framework are customized dental implant bridges. The Implant Bridge attaches directly to the endosseous dental implants and/or onto Nobel Biocare's Multi-unit Abutments with clinical screws and provides a platform for restoration.	NA	NA	NA	NA

Technological Characteristics						
Compatible Implant/Abutment and platform sizes	Nobel Biocare dental implants connections: - Internal Conical Connection: NP, RP, WP - Internal Tri-Channel: NP, RP, WP, 6.0 - External Hex: NP, RP, WP Nobel Biocare dental abutment and platform sizes: - Multi-unit Abutment (MUA): NP, RP, WP - Multi-unit Abutment (MUA) Plus: NP, RP, WP	Nobel Biocare dental implants connections: - Internal Conical Connection: NP, RP, WP - Internal Tri-Channel: NP, RP, WP, 6.0 - External Hex: NP, RP, WP Nobel Biocare dental abutment and platform sizes: - Multi-unit Abutment (MUA): NP, RP, WP	NA	NA	NA	NA
Device Material	Zirconium Oxide: Yttria-stabilized tetragonal zirconia (Y-TZP)	Zirconium Oxide	Zirconium Oxide: Yttria-stabilized tetragonal zirconia (Y-TZP)	Zirconium Oxide	NA	NA
	Titanium vanadium alloy	Titanium vanadium alloy	NA	NA	Titanium vanadium alloy	Titanium vanadium alloy
Surface	Anodization: Clinical Metal Adapter - for Internal Conical Connection implants DLC (Diamond Like Carbon) coating: Prosthetic Screw MUA Omnigrip Mini	Anodization: Clinical Metal Adapter - for Internal Conical Connection implants	NA	NA	DLC (Diamond Like Carbon) coating: Abutment screw	DLC (Diamond Like Carbon) coating (MediCarb): Elos Abutment screws
Bridge Design (restoration type)	Individualized full anatomic contour or framework	Individualized full anatomic contour or framework	NA	NA	NA	NA
Bridge Design: Arc Length	2 to 14 units	2 to 14 units	NA	NA	NA	NA
Number of Implants per Dental Bridge	2 to 10 implants	2 to 14 implants	NA	NA	NA	NA
Bridge Design: Angulated Screw Channel (ASC)	ASC CC: ASC feature available when the Dental Bridge is used in combination with Conical Connection implants. ASC MUA: ASC feature available when Dental Bridge is used in	ASC CC: ASC feature available when the Dental Bridge is used in combination with Conical Connection implants	NA	N/A	NA	NA

	combination with MUA and MUA plus Abutments.					
Angulated Screw Channel (ASC): Angulation	Screw Channel Angulation between 0° to 25°	Screw Channel Angulation between 0° to 25°	NA	N/A	NA	NA
Design method	CAD	CAD	NA	N/A	NA	NA
Manufacturing method	Dental Bridge: Industrialized manufacturing at NobelProcera manufacturing facility	FCZ Implant Bridge: Industrialized manufacturing at NobelProcera manufacturing facility	NA	N/A	NA	NA
	Clinical Metal Adaptors and Prosthetic Screws: Machined	Clinical Metal Adaptors: Machined	NA	N/A	NA	NA
Performance Testing						
Fatigue Performance	Fatigue testing using a modified version of ISO 14801.	Fatigue testing using a modified version of ISO 14801.	NA	Fatigue testing using a modified version of ISO 14801.	Fatigue testing using a modified version of ISO 14801.	NA
Biocompatibility	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2009	NA	N/A	Biocompatible according to ISO 10993-1:2018	NA

005-07 Performance Data

The fatigue limit of the Subject and Predicate Device was determined using a modified version of ISO 14801 (in saline solution) to reflect the clinical loading on bridges. Fatigue performance test was performed following the worst-case assessment. The Dental Bridge was manufactured from the Reference Device #1 Nacera Pearl (K143071), using the new connection with a MUA Plus as well as the Prosthetic Screw.

The differences in surface finish of the Prosthetic Screw were further supported by evaluation of the subject device according to FDA guidance for Industry and FDA Staff "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" dated May 12, 2004 to support substantial equivalence to the DLC coated abutment screw reference device.

A biocompatibility evaluation was conducted according to ISO 10993 – 1. The results demonstrated that biocompatibility testing consisting of cytotoxicity and chemical characterization using GC-MS analysis is appropriate to assess the biological safety of the subject device. Test samples are representative of the final finish subject device as they are made from the same material, manufacturing environments, and specifications as the subject device. The results demonstrate the biocompatibility of the subject device.

The subject device is provided non-sterile and is intended for single use only. The bridge and prosthetic screws are intended to be cleaned and sterilized prior to use. Validation for the cleaning and sterilization of the dental bridge and for the prosthetic screw was conducted. Sterilization validation was conducted per ISO 17665-1, ISO 17665-2, ANSI/AAMI ST79, and ANSI/AAMI TIR 12.

Both the Subject and Predicate Devices were tested under identical conditions. The results of the testing were used to address questions related to substantial equivalence based on difference in design between the Subject and Predicate Devices.

No clinical data was used to support the decision of Substantial Equivalence.

005-08 Conclusion

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the NobelProcera Zirconia Implant Bridge is deemed to be substantially equivalent to the Predicate Device.