April 28, 2023

Nobel Biocare AB
Bernice Jim
Head of RA Product Development and Marketed Products
Vastra Hamngatan 1
Goteborg, Vastra Gotaland SE 411 17
SWEDEN

Re: K223677
Trade/Device Name: Titanium Abutment Blank Nobel Biocare N1™ TCC
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: March 29, 2023
Received: March 29, 2023

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 -S

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)*
K223677

Device Name
Titanium Abutment Blank Nobel Biocare N1™ TCC

Indications for Use *(Describe)*
Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K223677

For Titanium Abutment Blank Nobel Biocare N1™ TCC

1. Submitter Information

Submitter:	Nobel Biocare AB P.O. Box 5190, 402 26 Västra Hamngatan 1 Goteborg, SE-411 17 Sweden
Submitted By:	Nobel Biocare Services AG Balz Zimmermann-Str. 7 8302 Kloten Switzerland
Contact Person:	Bernice Jim, PhD
E-Mail:	regulatory.affairs.nb@envistaco.com
Telephone number:	+41 43 211 42 00
Prepared by:	Nicole Fuchs/Corinne Larke-Grass
Date Prepared:	27 April 2023

2. Device Name

Proprietary Name:	Titanium Abutment Blank Nobel Biocare N1™ TCC
Manufacturer:	Nobel Biocare AB
Generic/Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Primary Product Code:	NHA
Secondary Product Code:	PNP

3. Predicate Device

Predicate Device

Proprietary Name:	Elos Accurate® Customized Abutment
Manufacturer:	Elos Medtech Pinol A/S
Generic/Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Primary Product Code:	NHA
Secondary Product Code:	PNP
Clearance:	K222044

Reference Device #1

Proprietary Name:	DESS Dental Smart Solutions
Manufacturer:	Terrats Medical SL

Generic/Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Primary Product Code:	NHA
Clearance:	K222288

Reference Device #2

Proprietary Name:	NobelProcera Ti Abutment Camlog Platforms
Manufacturer:	Nobel Biocare AB
Generic/Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	NHA
Clearance:	K122602

Reference Device #3

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

Reference Device #4

Proprietary Name:	Esthetic Abutments Nobel Biocare N1™
Manufacturer:	Nobel Biocare AB
Generic/Common Name:	Abutment, Dental, Endosseous
Regulation Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	NHA
Clearance:	K220339

4. Device Description

The Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured titanium abutment which can be customized via a validated CAD/CAM workflow in the dental office or dental laboratory to meet patient-specific anatomical requirements. The customization of the subject device is designed using a dental laboratory software and milled in the dental laboratory, using a Computer Aided Design (CAD)/Computer Aided Manufacturing (CAM) machine.

All digitally designed CAD/CAM customizations for the Titanium Abutment Blank Nobel Biocare N1™ TCC are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

The subject device has a premanufactured connection for the Nobel Biocare N1™ TCC TiUltra implants on one end and a premanufactured connection for the milling blank holder on the other end. These connections are not patient-specific.

The subject device is available for NP and RP implant platforms.

The subject device is used by dental healthcare professionals in dental offices and dental laboratories.

The subject device is composed of titanium vanadium alloy Ti6Al4V ELI (ISO 5832-3, ASTM F136) and features a surface with the same anodization already cleared in K211109.

It is an implantable single use device. The device is provided non-sterile and intended to be sterilized by the user prior to placement in the patient.

The Titanium Abutment Blank Nobel Biocare N1™ TCC is packaged with a Clinical Screw NB N1 TCC.

Table 1: Design Parameters

Subject Device	**301511 – Ti Abutment Blank NB N1 TCC NP Ø10 mm**	**301512 - Ti Abutment Blank NB N1 TCC RP Ø10 mm**
Maximum abutment angulation	30°	
Minimum screw channel thickness (min. wall thickness)	0.38mm	0.49mm
Maximum abutment height from implant level	16mm	
Minimum diameter	3.21mm	3.49mm
Maximum diameter	9.95mm	
Minimum post height	4.05mm	
Maximum post height	15.665mm	
Minimum gingival margin height	0.335mm	
Maximum margin height	4.6mm	

Principle of Operation / Mechanism of Action

The customized subject device acts as connecting element between a dental implant and a restoration. The mechanism of action is a mechanical screw connection, through the use of a clinical screw, and through a cemented connection to a restoration.

Compatible Devices:

The Titanium Abutment Blanks Nobel Biocare N1™ TCC are compatible with N1™ TiUltra TCC implants.

5. Indications for Use

Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units.
The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

6. Description of Substantial Equivalence

Overall, the subject device has the following substantial equivalences to the predicate device: similar intended use, the same operating principle, incorporates a similar basic design, incorporates the same materials, customizes to fit patient specific anatomical requirements, same methods of sterility and requires a digital dentistry workflow to manufacture at point of care .

Both subject and predicate abutment devices are premanufactured prosthetic components directly connected to the endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation. Therefore, the devices are substantially equivalent in the consideration of intended use and Indications for Use.

The technological differences between the subject and the predicate device do not affect the shared intended use nor raise different questions of substantial equivalence, as demonstrated by non-clinical testing.

Table 2 below shows the substantial equivalence comparison for the subject device.

Table 2: Titanium Abutment Blank Nobel Biocare N1™ TCC comparison table

Characteristic	Subject Device	Predicate Device	Reference Device #1	Reference Device #2	*Comparison*
	Titanium Abutment Blank Nobel Biocare N1 TCC	**Elos Accurate® Customized Abutment**	**DESS Dental Smart Solutions**	**NobelProcera Ti Abutment Camlog Platforms**	
	K223677	**K222044**	**K222288**	**K122602**	
Product Classification	Class II	Class II	Class II	Class II	*Identical*
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	*Identical*
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	*Identical*
Product Code, primary	NHA	NHA	NHA	NHA	*Identical*
Product Code, secondary	PNP	PNP	N/A	NHA	*Identical*
Review Panel	Dental	Dental	Dental	Dental	*Identical*
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Support of a prosthesis to restore chewing function.	--	--	*Similar intended use as the Primary Predicate expressed through a similar choice of words.*

Characteristic	Subject Device	Predicate Device	Reference Device #1	Reference Device #2	Comparison
	Titanium Abutment Blank Nobel Biocare N1 TCC	**Elos Accurate® Customized Abutment**	**DESS Dental Smart Solutions**	**NobelProcera Ti Abutment Camlog Platforms**	
	K223677	**K222044**	**K222288**	**K122602**	
Indications for Use	Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories	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 implant systems listed in Table 1: All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.	The NobelProcera Ti Abutments Camlog Platforms are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Camlog K series 3.3, 3.8, 4.3, 5.0 and 6.0 implants.	*Similar Indications for Use as the Primary Predicate expressed through a similar choice of words.*
Minimum wall thickness:	NP 0.38mm RP 0.49mm	0.4 - 0.5mm (Implant Platform dependent)	0.45mm	0.3mm --	*Similar as reference device #2. Substantial equivalence, as demonstrated by fatigue testing.*

Characteristic	Subject Device	Predicate Device	Reference Device #1	Reference Device #2	Comparison
	Titanium Abutment Blank Nobel Biocare N1 TCC	Elos Accurate® Customized Abutment	DESS Dental Smart Solutions	NobelProcera Ti Abutment Camlog Platforms	
	K223677	K222044	K222288	K122602	
Minimum gingiva height:	0.335 mm	0.5mm	0.3mm	--	*Similar as reference device #1. Substantial equivalence, as demonstrated by fatigue testing.*
Minimum diameter	NP Ø3.21mm RP Ø3.49mm	3.0 - 6.0 mm (Implant Platform dependent)	2.52 - 6.0 mm (Implant Platform dependent)	--	*Similar*
Minimum post height:	4.05mm	4mm	4mm	--	*Similar*
Abutment Shape	Patient specific	Patient specific	Patient specific	Patient Specific	*Identical*
Platform compatibility	Narrow Platform (NP) Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP)	3.3, 3.8, 4.3, 5.0, 6.0	*Identical*
Attachment method to implant	Screw retained	Screw retained	Screw retained	Screw retained	*Identical*
Prosthesis attachment method	Cement retained	Cement retained	Screw or cement retained	Cement retained	*Identical*
Restoration type	Single-unit and multi-unit (up to 3 units)	Single-unit and multi-unit	Single-unit and multi-unit	Single-unit	*Similar*
Design features	Pre-manufactured implant-interface connection, customizable cylindrical abutment body	Pre-manufactured implant-interface connection, customizable cylindrical abutment body	--	Pre-manufactured implant-interface connection, customizable cylindrical abutment body	*Identical*
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	--	Mechanical screw connection	*Identical*

Characteristic	Subject Device	Predicate Device	Reference Device #1	Reference Device #2	*Comparison*
	Titanium Abutment Blank Nobel Biocare N1 TCC	**Elos Accurate® Customized Abutment**	**DESS Dental Smart Solutions**	**NobelProcera Ti Abutment Camlog Platforms**	
	K223677	**K222044**	**K222288**	**K122602**	
Maximum abutment angulation	30°	30°/20° depending on the implant platform	30°	0°	*Identical*
Material	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	CP Titanium Titanium/vanadium alloy	*Identical*
Design Workflow	Kavo LS3, 3Shape Trios or other scanners with equal or higher accuracy than 6.9 µm 3Shape Abutment Designer Software (3Shape A/S) -K151455 AbutmentCAD (ExoCAD) - K193352 DTX Studio design (Nobel Biocare USA LLC) - K181932	3Shape scanner (3Shape A/S) 3Shape Abutment Designer Software (3Shape A/S) -K151455	--	Procera System Software (K053602)	*Similar to predicate. Substantial equivalence, as demonstrated by software verification and end-to-end workflow validation*
Manufacturing Workflow	CORiTEC by imes-icore	CORiTEC by imes-icore	--	--	*Identical*

7. Non-Clinical Test Data

The following performance tests were submitted in this 510(k) to support substantial equivalence and demonstrate that the subject device is as safe and as effective as its predicate device:

- **End user cleaning and sterilization validation** was conducted in accordance with *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff*, issued March 17, 2015 on the subject device.

- **Biocompatibility testing** was conducted in accordance with ISO 10993 on the subject device and no new issues regarding biocompatibility were raised for the subject device.
- **Fatigue Testing** was conducted on the worst-case system of the subject device and leveraged from K220339 in accordance with FDA Guidance "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*", issued May 12, 2004, to demonstrate the subject device is substantially equivalent to the predicate and reference devices.
- **Software verification and End-to-end workflow validation** was completed on the subject device with the compatible software and designated workflows to demonstrate that applicable restrictions are in place and cannot be modified by the user. To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the abutment blanks, validation testing of CAM restriction zones was conducted on the subject device, including verification to show avoidance of damage or modification of the connection geometry, and locking of restriction zones from user editing in the CAM software.
- **MRI compatibility** was leveraged from K212125 to demonstrate that the subject device is MR Conditional.

In conclusion, the results of the non-clinical testing demonstrated that the Titanium Abutment Blank N1™ TCC met the established performance specifications per intended use. The non-clinical testing also demonstrated that the Titanium Abutment Blank N1™ TCC does not raise different questions of substantial equivalence when compared to the respective predicate devices.

8. Clinical Performance Data

Clinical data was not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterized all performance aspects of the Subject Device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this device.

9. Conclusion

The Titanium Abutment Blank Nobel Biocare N1™ TCC was evaluated for substantial equivalence using standard and/or comparative testing. Based on a comparison of

intended use, Indications for Use, material composition, technological characteristics, features, and performance data the Titanium Abutment Blank Nobel Biocare N1™ TCC is at least as safe and effective as the predicate devices, and substantial equivalence to the predicate device is therefore supported.