



January 24, 2024

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

Re: K233208

Trade/Device Name: NobelProcera® Titanium ASC Abutment, Omnigrip Clinical Screw Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 28, 2023
Received: December 20, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Submission Number (if known)

K233208

Device Name

NobelProcera Titanium® ASC Abutments;
Omnigrip Clinical Screw Titanium

Indications for Use (Describe)

NobelProcera® Titanium ASC Abutments:

NobelProcera® Abutment Titanium is a patient-matched CAD/CAM prosthetic component directly connected to endosseous dental implants and is indicated for use as an aid in prosthetic rehabilitation.

Omnigrip Clinical Screw Titanium:

Clinical and Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements and are indicated 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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1 – 510(k) Summary – K233208

1.1 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.nb@envistaco.com
Telephone Number: +41 43 211 42 00
Prepared By: Nicole Fuchs, MLaw
Date Prepared: January 24th, 2024

1.2 Device Name No. 1

Proprietary name: NobelProcera® Titanium ASC Abutment
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

1.3 Device Name No. 2

Proprietary name: Omnigrip Clinical Screw Titanium
Manufacturer: Nobel Biocare AB
Common Name: Dental Abutment Screw
Classification Name: Endosseous Dental Implant Abutment
Regulation Number: 21 CFR 872.3630
Device Class: II
Product Code: NHA

1.4 Predicate Device

Primary Predicate Device No 1

Proprietary name: NobelProcera® Abutment Titanium (K091756)
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

Reference 1 for No. 1 Device

Proprietary 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: II
Product Code: NHA

Reference 2 for No. 1 Device

Proprietary name: DESS® Dental Smart Solutions (K221301)
Manufacturer: Terrats Medical SL
Common Name: Dental Abutment
Classification Name: Endosseous Dental Implant Abutment
Regulation Number: 21 CFR 872.3630
Device Class: II

Product Code: NHA, PNP

Reference 3 for No. 1 Device

Proprietary name: Universal Abutment NB N1 TCC (K211109)
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, PNP

Reference 4 for No. 1 Device

Proprietary name: NOBELACTIVE WIDE PLATFORM (WP) (K133731)
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

Reference 5 for No. 1 Device

Proprietary name: Titanium Abutment Blank Nobel Biocare N1™ TCC
(K223677)
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, PNP

Predicate No. 2 Device

Proprietary name: Omnigrip Clinical Screw CC (K132746)
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

Reference 1 for No. 2 Device

Proprietary name: NOBELACTIVE MULTI UNIT ABUTMENT (K072570)
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

Reference 2 for No. 2 Device

Proprietary name: Trefoil System (K170135)
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

Reference for No. 1 Device & No. 2 Device

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

1.5 Device Description Summary

The Subject Device NobelProcera® Titanium ASC Abutment is composed of two device lines: NobelProcera® Titanium ASC Abutment and the Clinical Screw Omnigrip Titanium.

NobelProcera® Titanium ASC Abutment is a patient matched CAD/CAM dental prosthesis which is connected to the Nobel Biocare implants featuring an internal conical and/or internal tri-channel connection, is available in the platform sizes NP, RP WP and

6.0 (for internal tri-channel connection only) and is intended for use as an aid in prosthetic rehabilitation to restore chewing function and esthetic appearance.

NobelProcera® Titanium ASC Abutments undergo patient matched customization at a Nobel Biocare production facility for the final, finished abutment device manufacturing.

NobelProcera® Titanium ASC Abutment is connected to the implant with a clinical screw and features an angulated screw channel which can be defined by the customer in an angulation (to the implant's axis) between 0° and 25°, in addition the abutment can be angulated to a maximum of 30°. The clinical screw features the Omnigrip Interface which allows tightening up to 25°.

NobelProcera® Titanium ASC Abutment and Omnigrip Clinical Screw Titanium are composed of titanium vanadium alloy Ti6Al4V ELI (ISO 5832-3, ASTM F136) and the surface of the abutments are provided with and without anodization and the Omnigrip Clinical Screw Titanium are provided with and without DLC coating.

The finished NobelProcera® Titanium ASC Abutment supports the placement of a cement-retained dental prosthesis.

Table 1-1 outlines the restorative design specifications for the NobelProcera Titanium ASC Abutments:

Table 1-1: Design Constraints

Subject Device	NobelProcera® Titanium ASC Abutment
Maximum abutment angulation	30°
Minimum screw channel thickness (min. wall thickness)	0.42 mm
Maximum abutment height from implant level	15 mm
Minimum diameter	4.4 mm
Maximum diameter	16 mm
Minimum post height (length above the abutment collar / gingival height)	4 mm
Maximum post height (length above the abutment collar / gingival height)	14.7 mm
Minimum gingival margin height	0.3 mm

Omnigrip Clinical Screw Titanium is available for the NP, RP, WP and 6.0 (for internal tri-channel connection only) platform, the devices connect the NobelProcera Titanium ASC Abutments to the dental implants. The devices feature an Omnigrip interface. Table 1-2 outlines the design specifications for the Omnigrip Clinical Screw Titanium:

Table 1-2: Omnigrip Clinical Screw Titanium Design Specifications

Connection	Largest nominal diameter	Nominal total length:
Conical	NP: 2.3 RP/WP: 2.525	NP: 7.325 RP/WP: 7.3
Tri-Channel	NP: 2.465 RP/WP/6.0: 2.465	NP: 8.315 RP/WP/6.0: 10.03

NobelProcera® Titanium ASC Abutment and Omnigrip Clinical Screw Titanium are compatible with Nobel Biocare implants featuring an internal conical connection (K142260, K073142, K173418 and K202344) and internal tri-channel connection (K023113).

1.6 Intended Use/Indication for Use

NobelProcera® Titanium ASC Abutments:

NobelProcera® Abutment Titanium is a patient-matched CAD/CAM prosthetic component directly connected to endosseous dental implants and is indicated for use as an aid in prosthetic rehabilitation.

Omnigrip Clinical Screw Titanium:

Clinical and Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

1.7 Indications for Use Comparison

The Intended Use statement and Indications for Use statement are the same, expressed through a similar choice of words.

1.8 Technological Comparison

1.8.1 NobelProcera® Titanium ASC Abutments

Table 1-3: NobelProcera Titanium ASC Abutment Predicate and Reference Device Summary

	Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
	NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
		K091756	K132746	K221301	K211109	
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Nobel Biocare AB	Terrats Medical SL	Nobel Biocare AB	
Product Classification	Class II	Class II	Class II	Class II	Class II	Same as Primary Predicate
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Primary Predicate
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Primary Predicate
Product Code, primary	NHA	NHA	NHA	NHA	NHA	Same as Primary Predicate
Product Code, secondary	N/A	N/A	N/A	PNP	PNP	Same as Primary Predicate
Review Panel	Dental	Dental	Dental	Dental	Dental	Same as Primary Predicate
Intended Use	Intended to be finalized into a single-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function	Nobel Biocare's NobelProcera®/Procera® Abutment Titanium/Zirconia is a customized dental abutment. The abutment attaches directly to the endosseous dental implant with a clinical screw and provides a	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	Support of a prosthesis to restore chewing function	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Same Intended Use expressed through a similar choice of words.

	Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
	NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
		K091756	K132746	K221301	K211109	
		platform for restoration.	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.			
Indications for Use	NobelProcera® Abutment Titanium is a patient-matched CAD/CAM prosthetic component directly connected to endosseous dental implants and is indicated for use as an aid in prosthetic rehabilitation.	Nobel Biocare's NobelProcera®/Procera® Abutment titanium/Zirconia is indicated for the treatment of partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function.	The NobelProcera Angulated Screw Channel Abutment Conical Connection are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	DESS Dental Smart Solutions abutments are intended for dental prosthetic restorations. DESS Dental Smart Solutions abutments are used as an interface between a dental implant or dental abutment and a dental	Universal abutments are indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible. The Universal Abutment consists of two major parts. Specifically, the titanium base and mesostructure	Same Indications for Use expressed through a similar choice of words and adjusted to match updated wording according to FDA feedback in prev. submissions (K220048).

	Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
	NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
		K091756	K132746	K221301	K211109	
				<p>restoration and will be attached to the implant or abutment using a prosthetic screw and attached to the dental restoration by cementing.</p> <p>All digitally designed custom abutments for use with Base abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic</p>	<p>components make up a two-piece abutment.</p> <p>The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.</p>	

		Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
		NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
			K091756	K132746	K221301	K211109	
					material, milling machine, and associated tooling and accessories.		
Technological Characteristics							
Device Dimensions/ Design Specifications							
Minimum wall thickness:		0.42 mm	0.3637mm	N/A	0.4 mm	N/A	Similar to Primary Predicate.
Platform compatibility	Conical Connection	NP, RP, WP	NP, RP	NP, RP	NP, RP, WP (according to 510k summary)	N/A	Similar to Primary Predicate. Same as Reference Device #2
	Tri Channel Connection	NP, RP, WP, 6.0	NP, RP, WP, 6.0	N/A	NP, RP, WP, 6.0 (according to 510k summary)	N/A	Same as Primary Predicate
	TCC	N/A	N/A	N/A	N/A	NP, RP	Same as Primary Predicate
Minimum platform diameter	NP CC	Ø 3.13	Ø 3.06	Ø 3.89	2.52 – 6.0 mm (Implant Platform dependent)	N/A	Similar to Primary Predicate and Same as Reference Device #2
	NP Tri-Chan	Ø 3.53	Ø 3.53	N/A		N/A	Same as Primary Predicate
	RP CC	Ø 3.46	Ø 3.46	Ø 4.29		N/A	Same as Primary Predicate

		Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
		NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
			K091756	K132746	K221301	K211109	
	RP Tri-Chan	Ø 4.3	Ø 4.3	N/A		N/A	Same as Primary Predicate
	WP CC	Ø 4.486	N/A	N/A		N/A	Similar as Primary Predicate Same as Reference Device #2
	WP Tri-Chan	Ø 5	Ø 5	N/A		N/A	Same as Primary Predicate
	6.0	Ø 6	Ø 6	N/A		N/A	Same as Primary Predicate
	TCC NP	N/A	N/A	N/A	N/A	Ø4.5mm	Same as Primary Predicate
	TCC RP	N/A	N/A	N/A	N/A	Ø4.5mm	Same as Primary Predicate
Minimum gingival height:		0.3 mm	N/A	N/A	0.3 mm	N/A	Same as Reference Device #2
Minimum post height: (length above the abutment collar / gingival height)		4mm	4mm	4mm	4mm	N/A	Same as Primary Predicate
Screw Channel		ASC (0°-25°)	Straight (0°)	ASC (0°-25°)	N/A	Straight (0°)	Similar to predicate. Same as Reference Device #1
Abutment Shape		Patient Specific	Patient Specific	Patient Specific	Patient Specific	Standard (bottom) / Patient specific (top)	Same as Primary Predicate
Attachment method to implant		Screw retained	Screw retained	Screw retained	Screw retained	Screw retained	Same as Primary Predicate
Prosthesis attachment method		Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Same as Primary Predicate
Restoration type		Single-unit and multi-unit	Single-unit and multi-unit	Single-unit	Single-unit and multi-unit	Single-unit	Same as Primary Predicate
Design features		Pre-manufactured implant-interface connection, customizable	Pre-manufactured implant-interface connection, customizable	Pre-manufactured implant-interface connection, customizable	N/A	Two-piece premanufactured abutment: customizable restoration and	Same as Primary Predicate

	Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
	NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
		K091756	K132746	K221301	K211109	
	cylindrical abutment body	cylindrical abutment body	cylindrical abutment body		standardized bottom	
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Same as Primary Predicate
Maximum abutment angulation	30°	20°	0°	30 max for Blanks	0°	Same as Reference Device #2
Material	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Adapter: Titanium/vanadium alloy	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Same as Primary Predicate
	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Abutment Body: Zirconium oxide	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Same as Primary Predicate
Surface Treatment	Anodization (Golden Abutment) & N/A (Non-Anodized Abutment)	N/A	N/A	N/A	Anodization	Same as Reference Device #3
Equipment for digital design workflow						
Design Workflow	Wax-up or CAD.	Wax-up or CAD.	N/A	3Shape Intraoral scanner Trios series, 3Shape E-series and D/R2000 Lab Scanner, 3Shape Abutment Designer Software (3Shape A/S) K151455	Scanner Kavo LS3, 3Shape Trios or other scanners with equal or higher accuracy than 6.9 µm Design software DTX Studio Design (K181932, where the implant libraries are	Same as Primary Predicate

	Subject Device	Primary Predicate Device	Reference Device #1	Reference Device #2	Reference Device #3	
	NobelProcera Titanium ASC Abutment	NobelProcera® Abutment Titanium	NobelProcera Angulated Screw Channel Abutment Conical Connection	DESS® Dental Smart Solutions	Universal Abutment NB N1 TCC	Comparison
		K091756	K132746	K221301	K211109	
					automatically included in the software installer) or 3Shape Abutment Designer Software (K151455, where the implant libraries are obtained via the 3Shape server in the software).	
Manufacturing Workflow	Customization milled at device manufacturer.	Customization milled at device manufacturer.	N/A	Digital Dentistry Workflow & Validated Milling Center	Milling unit - Indicated for Zirconia milling - Minimum 5 axis milling technology - Minimum 30.000 rpm spindle speed	Same as Primary Predicate

The similarities between the Subject Device line NobelProcera® Titanium ASC Abutments and the Primary Predicate Device are as follows:

- The design methods, manufacturing and packaging, compatible Implant/Abutment connection (CC and Tri-Ch) and platforms (NP/RP/WP/6.0) and utilized materials are identical for the Subject and Predicate Device.

- The Indications for Use of the Subject Device and the Primary Predicate Device is the same and expressed through a similar choice of words.
- Both the Subject Device and the Primary Predicate Device are labelled MR Conditional

Details of the Differences Between the Subject and Predicate Device:

There are no significant differences between the Subject and Predicate Devices but there are minor differences as follows:

- The minimum platform dimensions for the Conical Connection NP platform is different in the Subject and Predicate Device, however, the minimum device dimensions are within the range of the Predicate Device and Reference Device.
- The Subject Device has a maximum angulation of 30°, identical to Reference Device #2, whereas the Predicate Device has a maximum angulation of 20°.
- The Subject Device features an angulated screw channel, whereas the Predicate Device features a straight screw channel. This difference does not affect the shared intended use, between the devices as demonstrated by non-clinical testing. The same screw channel angulation (0° - 25°) is used for the Reference Device #1.
- The minimal wall thickness and gingival height of the Subject Device are similar and slightly greater than the Predicate Device.
- The Subject Device is provided with and without surface anodization, whereas the Predicate Device surface is not treated. The surface treated Subject Device features the same anodization already cleared in K211109.

Conclusion:

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

1.8.2 Omnigrip Clinical Screw Titanium

Table 1-4: Omnigrip Clinical Screw Titanium Predicate and Reference Device Summary

	Subject Device	Predicate Device	Comparison
	Omnigrip Clinical Screw Titanium CC NP Omnigrip Clinical Screw Titanium CC RP/WP Omnigrip Clinical Screw Titanium Tri-Channel NP Omnigrip Clinical Screw Titanium Tri-Channel RP/WP/6.0	Omnigrip Clinical Screw CC NP/RP/WP	
		K132746	
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Same as Predicate
Product Classification	Class II	Class II	Same as Predicate
Regulation Number / Name	21 CFR 872.3630 Endosseous Dental Implant Abutment	21 CFR 872.3630 Endosseous Dental Implant Abutment	Same as Predicate
Product Code, primary	NHA	NHA	Same as Predicate
Product Code, secondary	N/A	N/A	Same as Predicate
Review Panel	Dental	Dental	Same as Predicate
Intended Use	Intended for use to fasten dental implant system components to a dental implant or to another component.	Intended for use to fasten dental implant system components to a dental implant or to another component.	Same as Predicate
Indications for Use	Clinical and Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	Clinical Screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	Same as Predicate
Technological Characteristics			
Device Dimensions/ Design Specifications			
Screw body dimensions	Largest nominal diameter: CC NP: 2.3 CC RP/WP: 2.525	Largest nominal diameter: NP: 2.375 mm RP: 2.525 mm	Similar as Predicate

	TriCh NP: 2.465 TriCh RP/WP/6.0: 2.465		
	Nominal total length: CC NP: 7.325 CC RP/WP: 7.3	Nominal total length: NP: 8.905 mm RP: 8.705 mm	
	TriCh NP: 8.315 TriCh RP/WP/6.0: 10.03		
Compatible implant platform sizes	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP) 6.0	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Same as Predicate
Screw Interface	OmniGrip	OmniGrip	Same as Predicate
Principle of operation/ (Attachment method)	The Omnigrip clinical screws are used for securing the abutment to the endosseous implant.	The Omnigrip clinical screws are used for securing the abutment to the endosseous implant.	Same as Predicate
Material	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)"	Titanium vanadium alloy MTA 005 (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)"	Same as Predicate
Surface material	CC & TriCh NP: N/A (machined surface, no PVD (DLC) coating) CC RP/WP & TriCh RP/WP/6.0: PVD (DLC) surface treatment	NP: N/A (machined surface, no PVD (DLC) coating) ,Blue anodization on screw head RP/WP: PVD (DLC) surface treatment Blue anodization on screw head"	Similar as Predicate

The similarities between the Omnigrip Clinical Screw Titanium and the Predicate Device Omnigrip Clinical Screw CC NP/RP/WP are as follows:

- The Intended Use, Indications for Use, the Principle of operation, device material, compatible implant platform, thread design and screw interfaces are the same for both, Subject Device and the Predicate Device. Both devices are used to

fix a prosthetic component to a dental abutment. Furthermore, both, the Subject and Predicate Device are non-sterile, single-use devices.

Details of the Differences Between the Subject and Predicate Device:

There are no significant differences between the Subject and Predicate Devices but there are minor differences as follows:

- Both devices, Subject Device and Predicate Device, are provided with and without DLC (Diamond like carbon) coating, however, the screw head of the Subject Device is not anodized in comparison to the Predicate device.
- The Subject Device and Predicate Device have different screw body dimensions.
- The compatible abutment platforms of the Subject Device features either a conical connection (CC) or a Tri-Channel Connection (Tri-Ch) whereas the Predicate Device features a conical connection (CC).

Conclusion:

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

1.9 Non-Clinical and/or Clinical Tests Summary & Conclusions:

Non-clinical testing was performed on the Subject Device lines NobelProcera® Titanium ASC Abutment and Omnigrip Clinical Screw Titanium:

- 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)
- Magnetic Resonance compatibility testing according to ASTM F2052, ASTM F2213, ASTM F2119 and ASTM F2182. There are no significant changes to the materials and dimensions from the currently marketed Predicate Devices. Therefore, no new issues of electromagnetic compatibility are raised for the Subject Devices and they can be considered MR Conditional. The Subject Devices have obtained the status of MR Conditional per K212125. The MR Conditional tests were conducted according to FDA’s Guidance “Testing and Labeling Medical Devices for Safety in Magnetic Resonance (MR) Environment”.
- Verification of biocompatibility of the final device in accordance with ISO 10993-1. The Subject Devices are equivalent in material, surface, manufacturing processes, sterilization process, body contact and contact duration to the Reference Devices per K072570, K133731, K170135, K223677 therefore, no new issues regarding biocompatibility were raised.
- End user cleaning and sterilization validation in accordance with ISO 17665-1

Clinical performance data is not required to establish substantial equivalence for the Subject Devices.

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the two device lines NobelProcera® Titanium ASC Abutment and Omnigrip Clinical Screw Titanium are deemed to be substantially equivalent to the Predicate Devices.