February 21, 2019

Nobel Biocare AB
% Charlemagne Chua
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K173418
Trade/Device Name: NobelParallel™ Conical Connection
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: January 21, 2019
Received: January 22, 2019

Dear Charlemagne Chua:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173418

Device Name
NobelParallel™ Conical Connection

Indications for Use *(Describe)*

NobelParallel™ Conical Connection implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function.

NobelParallel™ Conical Connection implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

Implants with <7mm length are for delayed loading only when appropriate stability has been achieved.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K173418

510(k) Summary

I. Submitter

Submitted by:

Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Contact Person: Charlemagne Chua, Head Regulatory Affairs, US/CAN
Phone: (714) 282-4800 x7830
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Submitted for:

Nobel Biocare AB
Vastra Hamngatan 1
Goteburg, SE-411 17
Sweden

Date Prepared: February 21, 2019

II. Device

Device Proprietary Name:	NobelParallel™ Conical Connection
Common or Usual Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implants
Regulation Number:	21 CFR 872.3640
Product Code:	DZE
Device Classification	II

III. Predicate Device

The following device are referenced in the Substantial Equivalence Discussion

	Device Name	Applicant	510(k) Number
Primary Predicate	NobelActive®	NOBEL BIOCARE AB	K142660
Reference Devices	GROOVY IMPLANTS	NOBEL BIOCARE AB	K050258
	LEGACY3 6MM LENGTH IMPLANTS	IMPLANT DIRECT SYBRON MANUFACTURING LLC	K131097
	NobelSpeedy Groovy	NOBEL BIOCARE AB	K160119

IV. Device Description

NobelParallel™ Conical Connection (herein referred to as NobelParallel™ CC) implants are threaded, root-form, endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore a patient's chewing function.

The sterile, single-use only implants, made of commercially pure titanium (ASTM F67-13), range in length from 6.5 – 17.5 mm (physical implant length) and are provided in four (4) diameters (Ø 3.75 mm, 4.3 mm, 5.0 mm, and 5.5 mm). The implants feature a conical connection which is compatible with Nobel Biocare's narrow platform (NP), regular platform (RP), and wide platform (WP) abutments. The conical connections are color coded to identify the compatible abutment platform(s).

Each implant is individually packaged and provided with its corresponding titanium alloy cover screw (Ti-6Al-4V, per ASTM F136-13 and ISO 5832-3).

V. Indications for Use

NobelParallel™ Conical Connection implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function.

NobelParallel™ Conical Connection implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

Implants with <7mm length are for delayed loading only when appropriate stability has been achieved.

VI. Comparison of Technological Characteristics

The NobelParallel™ CC implants are similar to the predicate devices as follows:

- same implant/abutment connection type as the NobelActive Implant (K142260), and
- same implant body design, including slightly tapered walls and tapered apex with cutting flutes, as the NOBELSPEEDY™ Groovy Implants (K160119).

The NobelParallel™ CC implants are technologically different from the predicate devices as follows:

- the longest length of the subject device NobelParallel™ CC is within the range of predicate device NOBELSPEEDY™ Groovy,
- the smallest implant diameter of the subject device NobelParallel™ CC is within the range of the predicate device NobelSpeedy™ Groovy implants, and
- the use of new drill protocols is required.

Comparisons of the subject and predicate implants and cover screws are provided in the following tables.

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Comparison of Indications for Use Statements

ATTRIBUTE	Subject Device	Primary Predicate Nobel Biocare	Reference Device Nobel Biocare	Reference device Nobel Biocare	Reference device Implant Direct
	NobelParallel™ Conical Connection	**NobelActive® (K142260)**	**NobelSpeedy® Groovy (K160119)**	**NobelReplace MK III Groovy (K050258)**	**Legacy3 6mm (K131097)**
Indications for Use	NobelParallel™ Conical Connection implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelParallel™ Conical Connection implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary	NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing	Nobel Biocare's Groovy Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Groovy Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Groovy Implants may be placed immediately	The Legacy Dental Implant is a dental implant fixture that is a part of a two-piece implant system. The legacy implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

	delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with < 7mm length are for delayed loading only when appropriate stability has been achieved.	stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bicortical anchorage in cases of reduced bone density. NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied. Groovy implants are indicated for use in soft bone in posterior regions whenever immediate or early loading is applied. The Groovy implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants	

Comparison of Key Technological Characteristics

ATTRIBUTE	Subject Device	Primary Predicate Nobel Biocare -1	Reference device - 2 Nobel Biocare	Reference device - 3 Nobel Biocare	Reference device - 4 Implant Direct	Comments
	NobelParallel™ Conical Connection	NobelActive® (K142260)	NobelSpeedy® Groovy (K160119) incl. K050406	NobelReplace MK III Groovy (K050258)	Legacy3 6mm Length Implants (K131097)	
Thread Design	Double lead thread with groove	Double lead thread Reverse cutting flutes	Single lead thread with groove	Double lead thread with grooves	Double lead threaded	Double thread same as 1 Groove same as 2 Groove Same as 2
Connection Type	Internal Conical*	Internal Hex	External Hex	Internal Tri-channel	Leading bevel, a hex and a 1-72UNF thread	Same as 1
Implant Body Design	Tapered apex with bone cutting flutes, slightly tapered body	Expanding Taper Drilling blades on apex	Tapered apex with bone cutting flutes, slightly tapered body	Straight body design based on the Branemark Mk III Groovy. Slightly tapered apex but not like Speedy	Tapered body	Same as 2
Cutting Flutes	4 apical flutes	2 conical helix-shaped flutes, 1/3 turns (120°)	4 apical flutes	3 apical flutes	Unknown+	Same as 2
Implant length and diameter (physical dimensions)	Ø 3.75mm: 6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5 mm	Ø 3.5mm: 8.0, 9.5, 11.0, 12.5, 14.5, 17.5 mm	Speedy replace: Ø 3.5mm: 10.25, 11.75, 13.25, 15.25,	Ø 3.5mm: 9.25, 10.75, 12.25, 14.25 mm	Ø 3.7mm: 6mm;	**Length:** • Min length: 6.5 mm longer than 4 • other lengths same as 1

						Diameter: • Larger than 1,2,3 • Slightly smaller than 4
	Ø 4.3mm: 6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5 mm	Ø 4.3mm: 8.0, 9.5, 11.0, 12.5, 14.5, 17.5 mm	Ø 4.0mm: 7.25, 8.75, 10.25, 11.75, 13.25, 15.25, 18.25, 20.25, 22.25, 25.25 mm	Ø 4.0mm: 9.25, 10.75, 12.25, 14.25, 17.25 mm	Ø 4.2mm: 6mm;	**Length:** • Min length: 6.5 mm longer than 4 • other lengths same as 1 **Diameter:** • Larger/Same as 1, 2, 3, 4
	Ø 5.0mm: 6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5 mm	Ø 5.0mm: 8.0, 9.5, 11.0, 12.5, 14.5, 17.5 mm	Ø 5.0mm: 7.25, 8.75, 10.25, 11.75, 13.25, 15.25, 18.25 mm	-	Ø 4.7mm: 6mm; Ø 5.2mm: 6mm;	**Length:** • Min length: longer than 4 • other lengths same as 1 **Diameter:** • Larger/Same as 1, 2, 4
	Ø 5.5mm: 6.5, 8.0, 9.5, 11.0, 12.5, 14.5 mm	Ø 5.5mm: 6.5, 8.0, 9.5, 11.0, 12.5 mm	Ø 6.0mm: 7.25, 8.75, 10.25, 11.75, 13.25, 15.25, 18.25 mm	Ø 5.0mm: 9.25, 10.75, 12.25, 14.25, 17.25 mm	Ø 5.7mm: 6mm; Ø 7.0mm: 6mm;	**Length:** • Max length smaller than 2,3 • Other lengths same as 1 **Diameter:**

						• Larger/Same as 1, 3
Implant Diameter	3.75, 4.3, 5.0, 5.5 mm	3.5, 4.3, 5.0, 5.5 mm	3.5, 4.0, 5.0, 6.0 mm	3.5, 4.0, 5.0 mm	3.7, 4.2, 4.7, 5.2, 5.7, 7.0 mm	Different – see discussion
Connector Color	Magenta – Ø 3.75 mm NP Yellow – Ø 4.3 mm RP Yellow – Ø 5.0 mm RP Blue - Ø 5.5 mm WP	Magenta – Ø 3.5 mm NP Yellow – Ø 4.3 mm RP Yellow – Ø 5.0 mm RP Blue - Ø 5.5 mm WP	N/A	Magenta – Ø 3.5 mm NP Yellow – Ø 4.0 mm RP Blue - Ø 5.0 mm WP	Unknown+	Same
Compatible Abutments	Internal conical connection: NP Ø 3.0 mm RP Ø 3.4 mm WP Ø 4.4 mm	Internal conical connection: NP Ø 3.0 mm RP Ø 3.4 mm WP Ø 4.4 mm	External hex connection NP, RP, WP	Internal Tri-channel: NP, RP, WP	Unknown+	Same as 1
	K071370: Esthetic Abutment Conical Connection, Narrow Profile Abutment Conical Connection K072129: Procera® Esthetic Abutment Conical Connection K083100: GoldAdapt™ Non-Engaging Conical Connection	K071370: Esthetic Abutment Conical Connection, Narrow Profile Abutment Conical Connection K072129: Procera® Esthetic Abutment Conical Connection K083100: GoldAdapt™ Non-Engaging Conical Connection	-	-	Unknown+	Same as 1

	K133731: Healing Abutment Conical Connection K161416: Multi-unit Abutment Plus Conical Connection K161435: Temporary Snap Abutment Engaging K161655: On1 Base, Temporary Abutment, Esthetic Abutment, Healing Cap K160158: NobelProcera ASC Abutment Zirconia	K133731: Healing Abutment Conical Connection K161416: Multi-unit Abutment Plus Conical Connection K161435: Temporary Snap Abutment Engaging K161655: On1 Base, Temporary Abutment, Esthetic Abutment, Healing Cap K160158: NobelProcera ASC Abutment Zirconia				
Device Material	CP Titanium	CP Titanium	CP Titanium	CP Titanium	Titanium Alloy (Ti-6AL-4V ELI)	Same
Surface	TiUnite	TiUnite	TiUnite	TiUnite	SBM	Same
Sterilization method	Gamma	Gamma	Gamma	Gamma	Gamma	Same
SAL	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Unknown+	Same

* Previously named *Internal Hex*

+Unknown based on 510(k) summary

Comparison of Cover Screws

ATTRIBUTE	Subject device	Primary Predicate	Comments
	NobelParallel™ CC	NobelActive® (K142260)	
Design			
Material	Ti6Al4V	*Ti6Al4V*	Same
Surface	Anodization	Machined surface / Anodization	Same

Discussion

As seen above, the NobelParallel™ CC implant has the same internal conical connection (previously named Internal Hex) as the NobelActive Implants (K142260). Both the subject and the predicate devices are made of pure titanium and share the same TiUnite surface. Furthermore, the NobelParallel™ CC implant body follows the same design principles as the NOBELSPEEDY™ Groovy Implants (K160119), including the slightly tapered body and tapered apex with cutting flutes. The difference between the NobelParallel™ CC implants and the predicates is the availability of slightly larger outer diameters in the implants with diameters below 5.0 mm. The diameters are within the existing range of cleared implant diameters NobelActive implant (K142260) and Legacy3 6mm (K131097). Therefore, this difference does not raise questions substantial equivalence.

NobelParallel™ CC implant indications for use differ to the predicate device NobelActive Implants (K142260) in:

- Inclusion of a specific for short implants (< 7 mm) statement on limitations of loading protocols, which is not applicable to the predicate device as it is not available in length < 7 mm. The reference device Legacy3 6mm (K131097) indications for use include a similar statement on recognizing bone stability and appropriate occlusal load requirements.
- Exclusion of language regarding 3.0 diameter implants as the subject device is not available in 3.0 diameter.

The subject cover screws are made of the same material as the predicate and have slightly different geometry. Their surface is color coded, using an anodization technique, to identify the compatible implants.

VII. Performance Data

The following safety and performance data were provided in support of the substantial equivalence determination:

a. Clinical:
   - retrospective multi-center single cohort clinical study on NobelParallel Conical Connection short implant (<7mm).
b. Non-clinical:
   - comparative fatigue testing in accordance with ISO 14801;
   - comparative surface area analysis for short implants (<7 mm);
   - sterilization validation in accordance with ISO 11137-1:2006 + Amd 1:2013 and EN ISO 11137-2:2013;
   - packaging and transport validation in accordance with ISO 11607-1:2009 + Amd 1:2014;

- shelf-life studies in accordance with:
    - ASTM F1980-2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- endotoxin testing in accordance with:
    - USP <161 Medical Devices−Bacterial Endotoxin and Pyrogen Tests
    - ANSI/AAMI ST72:2011/ (R)2016 Bacterial endotoxins − Test methods, routine monitoring, and alternatives to batch testing

VIII. Conclusion

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. As seen above, the NobelParallel™ CC is the same or similar to the predicate devices in terms of intended use, materials of construction, design, size, surface treatment, and sterilization. The data within this submission support that the NobelParallel™ CC is substantially equivalent to the identified predicate/references devices.

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