December 4, 2018

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

Re: K183069
Trade/Device Name: NobelZygoma 0°
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 2, 2018
Received: November 5, 2018

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183069

Device Name
NobelZygoma 0°

Indications for Use *(Describe)*

NobelZygoma 0° implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches 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.

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.

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510(k) Summary
K183069

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Sweden

Submitted by:
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Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
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Date Prepared: November 28, 2018

DEVICE

Name of Device: NobelZygoma 0°

Common or Usual Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Primary Product Code: DZE

PREDICATE DEVICE

Primary predicate
Nobel Biocare – NobelZygoma 0º (K161598)

DEVICE DESCRIPTION

Implants:
Nobel Biocare's NobelZygoma 0° implants are threaded, root-form titanium dental implants intended to be integrated in the Zygomaticus bone to support prosthetic devices, such as artificial teeth, in order to restore chewing function.

The NobelZygoma 0º implants typically pierces the oral mucosa in the premolar region and passes through the sinus along the lateral wall of the maxilla. Depending on the contour of the lateral maxillary wall, the mid-portion of the implant may also pass lateral to the lateral wall.

The NobelZygoma 0° implants are available in lengths between 30 and 50 mm and have a 4.5 mm external hex connection. They are made of commercially pure titanium and have the Nobel Biocare TiUnite surface treatment.

INDICATIONS FOR USE

NobelZygoma 0º implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches 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.

Comparison of Technological Characteristics

Characteristic		CANDIDATE	PREDICATE	Comparison
		NobelZygoma 0°	NobelZygoma 0° (K161598)	
Features	Thread Design	Single lead thread	Single lead thread	Same
	Implant Body Design	Parallel wall with 3 diameters transition - 4.5 mm at the platform - 4.3 mm without thread at 9.5 mm from the platform - 5.0 mm at the apex at 18 mm from the apex Thread starts from the apex and extends for 18 mm	Parallel wall with 3 diameters transition - 4.5 mm at the platform - 4.3 mm without thread at 9.5 mm from the platform - 5.0 mm at the apex at 18 mm from the apex Thread starts from the apex and extends for 18 mm	Same
	Implant Tip Design	Tapered with cut out flutes.	Tapered with cut out flutes.	Same
	Implant Length	30, 35, 37.5, 40, 42.5, 45, 47.5, 50 mm	30, 35, 37.5, 40, 42.5, 45, 47.5, 50 mm	Same
	Connection Type	0° straight, regular platform	0° straight, regular platform	Same
	Platform design	External hex, 4.5 mm	External hex, 4.5 mm	Same
	Device Material	CP Titanium grade 4 (ASTM F67)	CP Titanium grade 4 (ASTM F67)	Same
	Surface	TiUnite	TiUnite	Same
Intended Use/ Principles of Operation		Nobel Biocare's Zygoma implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.	Nobel Biocare's Zygoma implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.	Same
Indications for Use		NobelZygoma 0º implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches 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	NobelZygoma 0º implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches 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.	Same

Analysis of Differences between Subject Device and Predicate

The subject NobelZygoma 0° implant is same as the predicate device (K161598). The modification is made to the packaging of the subject device. The original shrink wrap and outer label on the vial is modified by adding a blister as a second sterile barrier and a carrier cardboard box for the label. The new NobelZygoma 0° implant packaging is composed of 3 packaging layers - tertiary packaging, secondary packaging and primary packaging.The subject device is not being modified.

The packaging modification does not affect the intended use of the device or alter the fundamental scientific technology of the device. The intended use of the subject device, as described in its labeling, has not changed as a result of the packaging modifications.

PERFORMANCE DATA

Summary of Non-Clinical Testing:
The following verification/validation testing was performed on the modified implant packaging system. NobelZygoma 0° implant represents a worst case and data from the predicate device was leveraged to demonstrate substantial equivalence.

- Sterile Device Information
  - The sterilization method of the subject device is the same as the predicate device. The sterilization method is Gamma radiation and has been validated in accordance with ANSI/AAMI/SO 11137-1,2 & ISO 11737 1,2.

- Device Packaging
  - The packaging for the subject device is modified from the predicate device. Therefore, package integrity test, sterilization validation and biocompatibility of packaging was performed in accordance to: ISO 11607-1and ASTM F2096.

- Shelf Life
  - The packaging for the subject device is modified from that of the predicate with a 5-year expiration date labeled. Stability test - Accelerated aging was performed, on the new NobelZygoma 0° implant packaging composed of 3 packaging layers as per ASTM F1980, F2096 and ISO 11607-1 and real time aging is planned to validate 5 years expiration date.

CONCLUSIONS

The NobelZygoma 0° packaging system was evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics and non-clinical test data summarized in this submission, the subject NobelZygoma 0° has been shown to be substantially equivalent to the predicate NobelZygoma 0° Implant (K161598).