DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 16, 2016

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

Re: K152093
Trade/Device Name: NobelZygoma 45°
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 11, 2016
Received: February 12, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
-S

for Erin I. Keith, M.S.
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)*
K152093

Device Name
NobelZygoma 45°

Indications for Use *(Describe)*
Nobel Biocare's Zygoma 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 Zygoma Implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.

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)*

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

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A.4. 510(k) Summary

I. SUBMITTER

Nobel Biocare AB
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Submitted by:
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Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
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Date Prepared: July 24, 2015 (***revised March 10, 2016***)

II. DEVICE

Name of Device: NobelZygoma 45°
Common or Usual Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE

III.PREDICATE DEVICE

Nobel Biocare – Zygoma Implant (K070182)

IV. DEVICE DESCRIPTION

Nobel Biocare's NobelZygoma 45° implants are threaded, root-form titanium dental implants intended to extend through the maxillary sinus into the Zygomaticus bone to support prosthetic devices, such as artificial teeth, in order to restore chewing function.

The NobelZygoma 45° implants are available in lengths between 30 and 52.5 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.

V. INDICATIONS FOR USE

Nobel Biocare's Zygoma 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 Zygoma Implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.

VI. Comparison of Technological Characteristics

characteristic		CANDIDATE	PREDICATE
		NobelZygoma 45°	Zygoma Implant (K070182)
Features	Thread Design	Single lead thread	Single lead thread
	Implant Body Design	Parallel wall with 2 diameters transition at 2 mm from platform - 4.5 mm at the platform - 3.9 mm at the apex Threads starting 18 mm from apex	Parallel wall with 2 diameters transition at 13.7 mm from platform - 4.4 mm at the platform - 3.9 mm at the apex Threads starting 2.8 mm from apex
	Implant Tip Design	Tapered with cut out flutes.	Rounded with through hole
	Implant Length	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5 mm	30, 35, 40, 42.5, 45, 47.5, 50, 52.5 mm
	Connection Type	45° angled 4.0 mm external hex	45° angled 4.0 mm external hex
	Compatible Abutments	Zygoma system Multi-unit abutments	Zygoma system Multi-unit abutments
	Restoration compatibility	Fixed bar	Fixed Bar
	Device Material	CP Titanium grade 4	CP Titanium grade 4
	Surface	TiUnite	TiUnite
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.
Indications for Use		Nobel Biocare's Zygoma 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	Nobel Biocare's Zygoma 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

characteristic	CANDIDATE	PREDICATE
	NobelZygoma 45°	Zygoma Implant (K070182)
	restore patient esthetics and chewing function. The Zygoma Implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.	restore patient esthetics and chewing function. The Zygoma Implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

Analysis of Differences Between Subject Device and Predicate

The subject NobelZygoma 45° implants have a fundamentally similar design as the predicate Zygoma Implants (K070182). The two implant designs share the same materials, manufacturing methods, and use the TiUnite surface treatment. The two designs have the same 45° angulated platform and use the same abutments and surgical tooling. The two designs are available in lengths from 30 to 52.5 mm. The illustrations below show the subject NobelZygoma 45° implant next to the predicate Zygoma Implant.

NobelZygoma 45°

Zygoma Implant (K070182)

Although the subject and predicate devices share many similarities, a number of design characteristics have been changed. These changes are listed below.

- The tip of the NobelZygoma 45° has been modified to a tapered design with flutes to facilitate bone cutting. The predicate Zygoma Implant has a rounded tip with through hole.
- The threads of the NobelZygoma 45° start at the implant apex and extend 18 mm. The threads of the predicate start 2.8 mm from the apex and extend to the platform.
- The profile of the NobelZygoma 45° is different from the predicate. Both implants are parallel walled with 2 diameters. The NobelZygoma 45° has a diameter of 4.5 mm at the platform and a diameter of 3.9 mm starting from 2 mm below the platform. The predicate Zygoma Implant is 4.4 mm at the platform and 3.9 mm starting 13.7 mm from the platform

Summary:
These changes were made to modify the implant design to better adapt to situations of advanced jaw bone resorption in which Zygomatic implants are being used. The changes do not raise different questions of safety or effectiveness compared to the predicate. Differences in technology were evaluated through comparative performance testing.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:
Since the subject device does not represent a new worst case, data from the predicate device was leveraged in the following aspects of the 510(k).

- Sterile Device Information
    - The sterilization method for the subject device is the same as the predicate. The sterilization method is Gamma radiation and has been validated in accordance with ANSI/AAMI/ISO 11137. Therefore, no additional testing was required.
- Device Packaging
    - The packaging for the subject device is the same as the predicate. This is a titanium cylinder placed in a plastic vial with PVC shrink-wrap and tamper resistant strip. Therefore, no additional testing was required.
- Shelf Life
    - The packaging for the subject device is the same as the predicate and is labeled with a 5 year expiration date. Real time aging was used to determine the expiration dating. Therefore, no additional testing was required.
- Biocompatibility
    - The subject device is manufactured from the same material using the same manufacturing method as the predicate, has the same intended use, and the same patient contact type and duration. Therefore, no additional testing was required.

The fatigue limit of the NobelZygoma 45° was determined using a modified version of ISO 14801. The modifications to ISO 14801 were done to reflect the likely worst-case clinical use of the device. Both the subject and predicate device 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.

VIII. CONCLUSIONS

The NobelZygoma 45° was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the NobelZygoma 45° could be shown to not represent a worst-case with respect to the Zygoma Implant, data from the predicate device was leveraged to support the subject device. Based on technological characteristics and non-clinical test data included in this submission, the NobelZygoma 45° has been shown to be substantially equivalent to the Zygoma Implant.