DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 14, 2017

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: K161598
Trade/Device Name: NobelZygoma 0°
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 15, 2017
Received: February 16, 2017

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,

Michael J. Ryan -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)*
K161598

Device Name
NobelZygoma 0°

Indications for Use *(Describe)*
NobelZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch 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)

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)*

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510(k) Summary

I. SUBMITTER

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Submitted by:
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Date Prepared: March 13, 2017

II. 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
Other Product Codes: NHA

III. PREDICATE DEVICE

Primary predicate
Nobel Biocare – NobelZygoma 45º (K152093)

Reference predicates
Nobel Biocare – Zygoma Angled Abutments (K052885)
Nobel Biocare – Branemark System Zygomaticus Fixture System (K970499)
Nobel Biocare – Zygoma Implant (K070182)

IV. 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.

Abutments:
Nobel Biocare's NobelZygoma 0° abutments are implant abutments intended to be used with the NobelZygoma 0° implant only.

The NobelZygoma 0° abutments are used to accommodate the total angle of the implant – abutment joint. This is necessary since the subject implant has a flat platform rather than the 45° platform of the predicate device implants.

The NobelZygoma 0° abutments are available in lengths between 6 and 10 mm and with angle of 45° or 60°. They contain the external hex connection and are made of a titanium alloy without any additional coating.

Temporary Coping Multi-Unit:

The Temporary Coping Multi-Unit and Temporary Coping Plastic Multi-unit are premanufactured dental abutment directly connected to the Multi-unit abutment. It is used as a temporary aid in prosthetic rehabilitation until the final restoration is attached. Maximum intraoral use is 180-days.

V. INDICATIONS FOR USE

NobelZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygomaImplants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

VI. Comparison of Technological Characteristics

Implants:

characteristic		CANDIDATE	PREDICATE
		NobelZygoma 0°	NobelZygoma 45° (K152093)
Features	Thread Design	Single lead thread	Single lead thread
	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 2 diameters transition at 2 mm from platform - 4.5 mm at the platform - 3.9 mm at the apex Threads starting at apex and extending 18 mm
	Implant Tip Design	Tapered with cut out flutes.	Tapered with cut out flutes.
	Implant Length	30, 35, 37.5, 40, 42.5, 45, 47.5, 50 mm	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5 mm
	Connection Type	0° straight, regular platform	45° angled, regular platform
	Restoration Capability	Fixed bar	Fixed Bar
	Platform design	External hex, 4.5 mm	External hex, 4.5 mm
	Device Material	CP Titanium grade 4 (ASTM F67)	CP Titanium grade 4 (ASTM F67)
	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		NobelZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch 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.	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 manual are satisfied.

Abutments:

characteristic		CANDIDATE	PREDICATE
		NobelZygoma 0°	Zygoma Angled Abutments (K052885)
Features	Compatible Implant Platform	NobelBiocare: External Hex Regular Platform (RP)	NobelBiocare: External Hex Regular Platform (RP)
	Device material	Titanium-6 Aluminum-4 Vanadium alloy (ASTM F136)	Titanium-6 Aluminum-4 Vanadium alloy (ASTM F136)
	Angulations	45° and 60°	0° and 17°
	Available abutment length	45°: 6mm, 8mm and 10mm 60°: 6mm and 8mm	0°: 3mm and 5mm 17°: 2mm and 3mm
	Abutment design	Single piece with fixed upper shape	Single piece with fixed upper shape
	Screw material	Titanium-6 Aluminum-4 Vanadium alloy (ASTM F136)	Titanium-6 Aluminum-4 Vanadium alloy (ASTM F136)

Analysis of Differences between Subject Device and Predicate

Implants:

The subject NobelZygoma 0° implants have a fundamentally similar design as the predicate NobelZygoma 45º Implants (K152093). The two implant designs share the same materials, manufacturing methods, tapered tip design with flutes, and use the TiUnite surface treatment. Additionally, the threads of the NobelZygoma 0° and predicate both start at the implant apex and extend 18 mm. Although the subject and predicate devices share many similarities, a number of design characteristics have been changed. These changes are listed below.

- The available lengths for the NobelZygoma 0º are slightly different from the predicate. NobelZygoma 0º are available in lengths between 30 and 50 mm. The predicate device is available between the lengths of 30 and 52.5 mm.
- The profile of the NobelZygoma 0° is different from the predicate. Both implants are parallel walled. The NobelZygoma 0° have 3 diameters transition: 4.5 mm at the platform, 4.3 mm without thread at 9.5 mm at the platform and 5.0 mm at the apex at 18 mm from the apex. The predicate NobelZygoma 45º Implant is 4.5 mm at the platform and 3.9 mm at the apex.
- The abutment connection of the NobelZygoma 0º is flat. The predicate has a 45° angulation. This change requires different abutments that can compensate for the lack of platform angulation. This change does not increase the amount of total angulation used and allows placement of the implant independent of the head rotation.

Abutments:

The subject NobelZygoma 0° abutments, as well as the predicate abutments, share the common tip design of multi-unit abutments. The NobelZygoma 0º abutments are co-packed an abutment screw. Both, predicate and subject abutments also share the same material composition and manufacturing methods. Although many similarities, the abutments differ in the following aspects:

- The abutment angle was increased to accommodate the flat implant head of the subject implant device.
- The abutment length was increased in tandem with the angle, because the subject abutment needs to mimic the predicate devices angled implant head with the predicate abutment attached to it.

Summary:
These changes were made to modify the implant design to allow a more adaptable implant placement. The design changes to the abutment do not represent novel technologies and only of a kind to mimic the implant-abutment joint of the predicate device. Both, changes to subject implant and abutment accommodate each in other resulting in an implant-abutment joint which is similar to the implant-abutment joint of the predicates devices.

The Intended Use of the NobelZygoma 0º is substantially equivalent to the the NobelZygoma 45º (K152093, predicate). The change in the indication for use from “immediate function” to “immediate loading” better represents clinical experience and does not affect the intended use when compared to the predicate device.

The documentatjon submitted in the premarket notification demonstrates that the NobelZygoma 0º is substantially equivalent to the predicate device. Differences in technology were evaluated through comparative performance testing.

VII. PERFORMANCE DATA

Bench testing was performed to establish that the NobelZygoma 0° will withstand foreseeable mastication forces.

No clinical data was used to support the decision of safety and effectiveness.

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 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. The LAL testing information has been provided with this submission.

- Device Packaging
  - The packaging for the subject device is the same as the predicate device. This is a titanium cylinder placed in a plastic vial with PVC shrink-wrap and tamper resistant strip.

- Shelf Life
  - The packaging for the subject device is the same as the predicate and is labeled with a 5 year expiration date for implants and a 3

year expiration date for abutments. Accelerated aging was used to determine the expiration dating.

- 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.

The fatigue limit of the NobelZygoma 0° 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.

Discussion of Non-Clinical data:
In order to assess the differences between the predicate device and subject device comparability testing and/or evaluations were performed as listed above. The data obtained concluded that the subject devices are considered to be substantially equivalent with the identified predicate devices ..

VIII. CONCLUSIONS

The NobelZygoma 0° was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the NobelZygoma 0° 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 0° has been shown to be substantially equivalent to the NobelZygoma 45º Implant.