DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 25, 2016

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

Re: K160158
Trade/Device Name: NobelProcera HT ML FCZ Implant Bridge and Framework
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 14, 2016
Received: June 15, 2016

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. 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,

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)*

K160158

Device Name

NobelProcera HT ML FCZ Implant Bridge and framework

Indications for Use *(Describe)*

The NobelProcera® HT ML FCZ (full contour zirconia) and framework Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

A.4. 510(k) Summary

I. SUBMITTER

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

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

Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
Phone: (714) 282-4800 x 7830
Fax: (714) 998-9348

Date Prepared: July 15, 2016

II. DEVICE

Name of Device: NobelProcera HT ML FCZ Implant Bridge and Framework
Common or Usual Name: Endosseous Dental Implant Abutment
Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3640)
Regulatory Class: II
Product Code: NHA

III. PREDICATE DEVICE

Nobel Biocare – NobelProcera Implant Bridge Zirconia (K091907) Nobel Biocare – Angulated Screw Channel Abutment Conical Connection (K132746)

IV. DEVICE DESCRIPTION

The NobelProcera HT ML FCZ Implant Bridge and Framework is an individualized implant supported screw-retained dental implant bridge for the partially dentate and edentulous patients.

The NobelProcera HT ML FCZ Implant Bridge and Framework is available as either a framework requiring veneering in a dental lab or as a full anatomic contour design requiring minimum laboratory processing. The NobelProcera HT ML FCZ Implant Bridge and Framework is available for bridges between 2 to 14

units. The bridge is made of a titanium base and a highly transparent multi layered zirconia material which is available in 6 shades.

The NobelProcera HT ML FCZ Implant Bridge and Framework is available for the Nobel Biocare internal conical connection, external hex, and internal tri-channel implants and the Multi-unit abutments.

V. INDICATIONS FOR USE

The NobelProcera® HT ML FCZ (full contour zirconia) and framework Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological characteristics		Subject Device	Predicate
		NobelProcera HT ML FCZ Implant Bridge and Framework	NobelProcera Implant Bridge Zirconia (K091907)
Design Features	Compatible Implant /Abutment Platform	Nobel Biocare Internal Conical Connection NP, RP, WP Internal Tri-Channel NP, RP, WP, 6.0 External Hex NP, RP, WP Multi-unit NP/RP, WP	Nobel Biocare Internal Conical Connection NP, RP, WP Internal Tri-Channel NP, RP, WP, 6.0 External Hex NP, RP, WP Multi-unit NP/RP, WP Astra Tech Yellow, Aqua, Lilac Straumann Octagon 3.5, 4.8, 6.5 Bone Level 3.3, 4.1/4.8 Biomet 3i Internal 3.4, 3.75/4.0, 5.0, 6.0 External 3.4, 4.1, 5.0, 6.0 Zimmer Screw-Vent 3.5, 4.5, 5.7 AdVent 4.5
	Device Material	Zirconium Oxide with titanium vanadium alloy implant interface for Internal Conical Connection.	Zirconium Oxide
	Bridge Design	Individualized full anatomic contour or framework	Individualized framework
	Arc Length	2 to 14 units	2 to 14 units
	Design method	CAD	Wax-up or CAD design

Technological characteristics	Subject Device	Predicate
	NobelProcera HT ML FCZ Implant Bridge and Framework	NobelProcera Implant Bridge Zirconia (K091907)
Manufacturing method	Industrialized manufacturing at NobelProcera manufacturing facility	Industrialized manufacturing at NobelProcera manufacturing facility
Intended use	The NobelProcera HT ML FCZ Implant Bridge and Framework are customized dental implant bridges intended to restore chewing functions. The Implant Bridge is intended to directly attaches to the endosseous dental implants and/or onto Nobel Biocare's Multi-unit Abutments with clinical screws and provides a platform for restoration.	The NobelProcera Implant Bridge Zirconia is a bridge framework that attaches to implants or abutments. The NobelProcera Implant Bridge Zirconia is intended to be finished into a dental prosthesis using standard laboratory dental materials such as resin composite or porcelain veneer.
Indication for Use	The NobelProcera® HT ML FCZ (full contour zirconia) and framework Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	The NobelProcera Implant Bridge Zirconia is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The difference in the Indications for Use for the subject device is the addition of the term "bridge anatomically shaped" allows for an anatomically shaped bridge as compared to just a bridge framework in the primary predicate device. The addition of an anatomically shaped bridge does not change the intended use of the implant bridge dental abutment device.

The additional difference between the subject device and the primary predicate is the inclusion of a titanium interface between the zirconia material and the implant body. The reference predicate [K132746] supports the addition of a titanium interface between the zirconia material and the implant body.

VII. PERFORMANCE DATA

The fatigue limit of the NobelProcera HT ML FCZ Implant Bridge and Framework 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.

Validation of the recommended sterilization parameters was conducted according to ISO 17665-1 and ISO 17665-2.

Cytotoxicity testing according to ISO 10993-5 as well as BC-MS analysis for leacables/extractable was conducted on the ISO 6872 ceramic and ASTM F136 titanium alloy material composition of the device.

No clinical data was used to support the decision of substantial equivalence.

VIII. CONCLUSIONS

The NobelProcera HT ML FCZ Implant Bridge and Framework was evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics and non-clinical test data included in this submission, the NobelProcera HT ML FCZ Implant Bridge and Framework has been shown to be substantially equivalent to the NobelProcera Implant Bridge Zirconia.