DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 22, 2016

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

Re: K162043
Trade/Device Name: NobelProcera® HT ML FCZ Bridge
Regulation Number: 21 CFR 872.3920
Regulation Name: Porcelain Tooth
Regulatory Class: Class II
Product Code: ELL
Dated: October 25, 2016
Received: October 26, 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,

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)*

K162043

Device Name
NobelProcera® HT ML FCZ Bridge

Indications for Use *(Describe)*

NobelProcera® HT ML FCZ Bridge is indicated for use as core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function.

NobelProcera® HT ML FCZ Bridge is indicated for use as a bridge that will be cemented on natural teeth or artificial abutments.

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

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Submitted by:
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22715 Savi Ranch Parkway
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Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
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Date Prepared: October 25, 2016

II. DEVICE

Name of Device: NobelProcera HT ML FCZ Bridge
Common or Usual Name: Porcelain tooth
Classification Name: Porcelain tooth (21 CFR 872.3920)
Regulatory Class: II
Product Code: ELL

III. PREDICATE DEVICE

Primary predicate:
Nobel Biocare – NobelProcera HT ML Full Contour Zirconia Crown (K153534)

Reference predicates:
Nobel Biocare – Procera Bridge Zirconia (K071182)
Kuraray Noritake Dental Inc. – Katana Zirconia (K143439)

IV. DEVICE DESCRIPTION

NobelProcera® HT ML FCZ Bridge is an individualized cement retained dental restoration manufactured from translucent multi-layered zirconia material.

NobelProcera® HT ML FCZ Bridge is intended to be a replacement for a natural teeth. After finalizing the NobelProcera® HT ML FCZ Bridge in the dental laboratory, it is cemented or bonded on prepared teeth or artificial abutments by a clinician, to provide a natural tooth like appearance and to restore chewing functionality in the patient's mouth. To achieve esthetics and required value and chroma of the surrounding natural teeth the NobelProcera® HT ML FCZ Bridge is suitable for cut-back (veneering) or stain and glaze techniques.

The design of the NobelProcera® HT ML FCZ Bridge is determined in a dental laboratory, hospital or dental practice by scanning, designing and ordering the bridge using NobelDesign or supported third party CAD systems. The bridge, once ordered, is sent electronically to one of NobelProcera's centralized milling centers for fabrication.

The NobelProcera® HT ML FCZ Bridge is manufactured from a solid piece of yitria-stabilized tetragonal zirconia. It is available in 6 shades and for bridges between 2 and 14 units.

V. INDICATIONS FOR USE

NobelProcera® HT ML FCZ Bridge is indicated for use as core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function.

NobelProcera® HT ML FCZ Bridge is indicated for use as a bridge that is cemented on natural teeth or artificial abutments.

VI. Comparison of Technological Characteristics

Characteristic		Candidate	Primary Predicate	Reference Predicate	Reference Predicate
		NobelProcera HT ML FCZ Bridge	NobelProcera HT ML Full Contour Zirconia Crown (K153534)	Procera Bridge Zirconia Extended Units (K071182)	Katana Zirconia (K143439)
Features	Material	Y-TZP Zirconium Oxide (Katana Zirconia K143439)	Y-TZP Zirconium Oxide (Katana Zirconia K143439)	Y-TZP Zirconium Oxide	Y-TZP Zirconium Oxide
	Shape	Full anatomic contour with partial cut-back option	Full anatomic contour with partial cut-back option	Core structure (framework) for a bridge	N/A
	Design Method	CAD	CAD	CAD	N/A
	Manufacturing Method	Nobel Biocare in-house CAM	Nobel Biocare in-house CAM	Nobel Biocare in-house CAM	N/A
	Number of units	2-14 units	Individual crown	2-14 units	N/A
	Minimum Thickness	0.6 mm	0.4 mm (Anterior) 0.7 mm (Pre-molar and Molar)	0.6 mm	N/A
Intended Use/Principles of Operation		The NobelProcera HT ML FCZ Bridge is an individualized cement retained dental restoration. It is intended to be a replacement for natural teeth.	The NobelProcera HT ML Full Contour Zirconia Crown is an individualized cement retained dental restoration. It is intended to be a replacement for natural teeth.	The Procera Bridge Zirconia is an individualized cement retained dental restoration. It is intended to be a replacement for natural teeth	Katana Zirconia is used for the fabrication of the all-ceramic restorations (frameworks, FCZ crowns, FCZ bridges, inlays, onlays and veneers.)
Indications for Use		NobelProcera HT ML FCZ Bridge is indicated for use as core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. NobelProcera HT ML FCZ Bridge is indicated for use as a bridge that is cemented on natural teeth or artificial abutments.	NobelProcera HT ML Full Contour Zirconia Crown is indicated for use as core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. NobelProcera HT ML Full Contour Zirconia Crown is indicated for use as single crown that will be cemented to a natural or artificial tooth abutment.	Nobel Biocare's Procera Bridge Zirconia is indicated for use as the core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. The Procera Bridge Zirconia may be cemented or bonded to either natural or artificial tooth abutments.	KATANA Zirconia is used for the fabrication of the all-ceramic restorations (frameworks, FCZ crowns, FCZ bridges, inlays, onlays and veneers.)

Analysis of Differences Between Subject Device and Predicates

The NobelProcera HT ML FCZ Bridge differs from the primary predicate NobelProcera HT ML Full Contour Zirconia Crown (K153534) in the number of units available. As a crown the primary predicate is intended only to be used on a single tooth. The subject device is a bridge intended for 2 to 14 unit restorations.

The subject device uses the same high translucent multi layer Katana material (reference predicate K143439) as the primary predicate K153534. This material is cleared for the fabrication of full contour bridges such as the subject NobelProcera HT ML FCZ Bridge. The number of units available for the subject bridges is the same as the reference predicate Procera Bridge Zirconia (K071182).

Intended Use:
The NobelProcera HT ML FCZ Bridge and primary predicate NobelProcera HT ML Full Contour Zirconia Crown have the same intended use. They are individualized cement retained dental restorations intended to be a replacement for natural teeth.

Summary:
The changes detailed above do not raise different questions of safety or effectiveness compared to the predicates.

VII. PERFO RMANCE 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 aspect of the 510(k).

- Biocom patibility
    - The subject device is manufactured entirely from the zirconia cleared under K143439. It is manufactured using the same method as the predicate (K153534). The subject device has the same intended use, patient contact type, and duration as the predicate. Therefore, no additional testing was required.

- Perform ance Data
    - The NobelProcera HT ML FCZ Bridge is made entirely from the Katana Zirconia material cleared under K143439. Since this predicate material is intended to be used in the manufacture of bridge such as the subject device, no additional performance testing is necessary.

VIII. CONCLUSIONS

The NobelProcera HT ML FCZ Bridge was evaluated for substantial equivalence. Based on technological characteristics, the NobelProcera HT ML FCZ Bridge has been shown to be substantially equivalent to the NobelProcera HT ML Full Contour Zirconia Crown (K153534).