DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 6, 2016

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

Re: K153534
Trade/Device Name: Nobelprocera Ht Ml Full Contour Zirconia Crown
Regulation Number: 21 CFR 872.3920
Regulation Name: Porcelain Tooth
Regulatory Class: Class II
Product Code: ELL
Dated: December 8, 2015
Received: December 9, 2015

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,

Susan Runner DDS, MA

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)*

K153534

Device Name
NobelProcera HT ML Full Contour Zirconia Crown

Indications for Use *(Describe)*

NobelProcera HT ML FCZ 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 FCZ Crown is indicated for use as single crown that will be cemented to a natural or artificial tooth abutment.

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

Submitted by:
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Submitted for:
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Goteborg, SE-411 17
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Date Prepared: ***June 1, 2016***

II. DEVICE

Name of Device: NobelProcera HT ML Full Contour Zirconia Crown
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 – Procera Copings and Pontic (K032562)

Reference predicate:
Kuraray Noritake Dental Inc. – Katana Zirconia (K143439)

IV. DEVICE DESCRIPTION

NobelProcera® HT ML FCZ (High Translucent Multi Layered Full Contour Zirconia) Crown is an individualized dental restoration made from translucent multi-layered zirconia material.

NobelProcera® HT ML FCZ Crown is intended to be a replacement for a natural tooth. After finalizing the NobelProcera® HT ML FCZ Crown in the dental laboratory, it is cemented or bonded onto a tooth or artificial abutment, 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 Crown is suitable for cut-back (veneering) or stain and glaze techniques.

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

V. INDICATIONS FOR USE

NobelProcera HT ML FCZ 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 FCZ Crown is indicated for use as single crown that will be cemented to a natural or artificial tooth abutment.

VI. Comparison of Technological Characteristics

Characteristic		Candidate NobelProcera Full Contour Zirconia Crown	Primary Predicate Procera Coping and Pontic (K032562)	Reference Predicate Katana Zirconia (K143439)
Features	Material	Zirconium Oxide (Katana Zirconia K143439)	Zirconium Oxide Aluminum Oxide	Zirconium Oxide
	Shape	Full anatomic contour	Fixed thickness	N/A
	Design Method	CAD	CAD and Wax-up	N/A
	Manufacturing Method	Nobel Biocare in-house CAM	Nobel Biocare in-house CAM	N/A
	Thickness	0.4mm (Anterior) 0.7 mm (Pre-molar and Molar)	0.4 mm and 0.6 mm	N/A
Intended Use/Principles of Operation		NobelProcera Full Contour Zirconia Crowns are intended for use as an aid in prosthetic rehabilitation	Intended for use as core structures of a prosthetic device for the oral cavity.	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 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 FCZ Crown is indicated for use as single crown that will be cemented to a natural or artificial tooth abutment.	Nobel Biocare's Procera Copings and Pontic are indicated for use as core structures of an artificial prosthesis, i.e. a three-unit bridge, for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. The Pontic is indicated as the core structure of the center unit and the Copings are indicated as the core structures of the two side crowns, thereby forming the three-unit bridge. The Copings are also indicated for use as single crowns that will be cemented to a natural or artificial tooth abutment in the treatment of partially edentulous patients in order to restore chewing function.	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 predicate Nobel Biocare Procera Copings and Pontic contain both crown and pontic. When two copings are used in conjunction with a pontic a three-unit bridge may be made. In addition to the use as a three-unit bridge the copings of the predicate, when used independently, are indicated for use as a single crown. The subject device is only indicated for single crown use. The change in Indication for Use for the subject device to only a single crown does not affect the determination of substantial equivalence since single crown use is within the previously cleared predicate Indications for Use.

The NobelProcera HT ML Full Contour Zirconia Crown is made entirely of the Katana Zirconia predicate material (K143439) which is cleared for the fabrication of full contour crowns such as the subject device.

The primary difference between the NobelProcera HT ML Full Contour Zirconia Crown and the predicate Procera Coping and Pontic (K032562) is that the subject device is made in an anatomic full contour tooth shape or a cut-back. The full contour crown is produced with the intention to create the final tooth shape, made entirely from solid zirconia. The predicate NobelProcera Coping looks more like a “shell” that must be built up with dental ceramic so that the dental technician can create the final tooth shape.

Intended Use:
The difference between the subject device and predicate intended uses are related to the specific role within the process of making a crown that the device is intended to fulfill. In the case of the Procera Coping and Pontic (K032562) the coping is the core of a crown rather than the full crown shape of the subject device. The Katana Zirconia (K143439) intended use is that of a porcelain powder for clinical use (872.6660) used in the manufacture of the subject device.

Summary:
The changes detailed above do not raise different questions to support substantial equivalence determination.

VII. PERFORMANCE DATA

No clinical or non-clinical test data was used to support the substantial equivalence determination.

VIII. CONCLUSIONS

The NobelProcera HT ML Full Contour Zirconia Crown was evaluated for substantial equivalence. Based on technological characteristics, the NobelProcera HT ML Full Contour Zirconia Crown has been shown to be substantially equivalent to the NobelProcera Coping and Pontic.