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

October 26, 2017

Re: K171142
Trade/Device Name: Healing Cap Multi-Unit Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 22, 2017
Received: September 25, 2017

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 (DICE) 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 (DICE) 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,

Mary S. Runner -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)*
K171142

Device Name
Healing Cap Multi-unit Titanium

Indications for Use *(Describe)*
The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.

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.

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510(k) Summary

I. SUBMITTER K171142

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Submitted by:
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Date Prepared: March 31, 2017

II. DEVICE

Name of Device: Healing Cap Multi-Unit Titanium
Common or Usual Name: Dental Abutment Healing Cap
Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)
Regulatory Class: II
Product Code: NHA

III. PREDICATE DEVICE

Primary Predicate:
Nobelpharma Branemark System – Healing Cap (K925780)

Reference Predicate:
Multi-unit Abutment Plus (K161416)

IV. DEVICE DESCRIPTION

The Healing Cap Multi-unit Titanium is a transmucosal extension secured to Nobel Biocare Multi-unit Abutments. It is intended to be used during intra-oral soft tissue healing to protect the internal connection of the MUA Multi-unit Abutments and prepare the soft tissue for the prosthetic procedure (temporary and final restoration). It has a maximum intra-oral use of 180-days.

The Healing Cap Multi-unit titanium portfolio consist of 6 healing cap variants. There are two different caps designs, two heights, and three diameters to accommodate the gingival anatomy and to provide the dentist with options for abutment shoulder visibility and soft tissue retraction.

V. INDICATIONS FOR USE

The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological characteristics		Subject Device	Predicate
		Healing Cap Multi-unit Titanium	Nobelpharma Branemark System - Healing Caps (K925780)
Design Features	Healing Cap Design	One-piece Healing Cap - Titanium with integrated screw	One-piece Healing Cap - Titanium with integrated screw Two-piece Healing Cap - Plastic abutment (Santoprene or Polymethylpentene) with stainless steel screw
	Materials	Titanium alloy Ti6Al4V ELI (ASTM F136)	One-piece Healing Cap - Grade 2 CP titanium Two-piece Healing Cap - Santoprene 273-50 or - Polymethylpentene grade RT18 - Stainless Steel screw
	Healing Cap Height	4.1 and 5.5 mm	Titanium - 2.5 mm Plastic - 2.7, 3.5 mm (not including screw protrusion)
	Healing Cap Diameter	5.0, 6.0, 6.9 mm	Titanium - 4.5 mm Plastic - 4.5, 6.5 mm
Compatible abutments		Nobel Biocare Multi Unit Abutments (K072570, K161416, K093643, K061477)	NobelPharma Titanium Abutment Complete (K925769)
Intended use		The Healing Cap Multi-unit Titanium is intended to be used with Multi-unit abutments during soft tissue healing.	The Healing Caps are intended to be used during the second healing stage to protect the internal threads of the abutment and protect the mucosal tissue.
Indication for Use		The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.	No indication statement in submission.

Analysis of Differences Between Subject Device and Predicate

The subject device Healing Cap Multi-unit Titanium is a single-piece healing cap made entirely of titanium alloy (ASTM F-136). The predicate Nobelpharma Branemark System – Healing Cap (K925780) has both one-piece healing abutments made entirely of CP titanium and two-piece designs made of plastic with integrated stainless steel screws.

Both subject and predicate devices are intended to be connected to the dental abutment as temporary components during soft tissue healing. The Healing Cap Multi-unit Titanium has a maximum intra-oral use of 180-days.

The subject healing caps are available in three diameters to fit the compatible abutments and two heights that allow the dentist to adapt to the existing soft tissue. The predicate single-piece healing cap is available in only one diameter and height combination. Details regarding the available sizes are in the table above.

The subject healing cap is made of titanium alloy Ti6Al4V ELI (ASTM F136). The predicate single-piece healing Cap is made entirely of commercially pure titanium. The use of titanium alloy will not have an impact on the use of the healing cap.

Summary:
The documentation submitted in the premarket notification demonstrates that the Healing Cap Multi-unit Titanium is substantially equivalent to the predicate device.

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 reference 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 reference predicate. This is a thermoform tray with peel top lid. Therefore, no additional testing was required.
- Shelf Life
    - The packaging for the subject device is the same as the reference predicate and is labeled with a 3-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 as the reference predicate, uses 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.

VIII. CONCLUSIONS

The Healing Cap Multi-unit Titanium was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the Healing Cap Multi-unit Titanium could be shown to not represent a worst-case with respect to the predicates, data from these predicate devices was leveraged to support the subject device. Based on technological characteristics, the Healing Cap Multi-unit Titanium has been shown to be substantially equivalent to the NobelPharma Branemark System Healing Caps (K925780).