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

March 16, 2017

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

Re: K161416
Trade/Device Name: Multi-unit Abutment Plus
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 10, 2017
Received: February 13, 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)*

K161416

Device Name
Multi-unit Abutment Plus

Indications for Use *(Describe)*

The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

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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Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
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Date Prepared: March 15, 2017

II. DEVICE

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

III. PREDICATE DEVICE

Primary Predicate:
NobelActive Multi Unit Abutment - K072570

Reference Predicate
NobelActive Wide Platform (WP) – K133731

IV. DEVICE DESCRIPTION

Multi Unit Abutment Plus
The Multi-unit Abutment Plus are transmucosal abutments used for multiple unit screw retained restorations. The abutment family consists of straight and angled abutments in varying collar heights. The non-angled abutments have a built in screw and the angled abutments are co-packed with a separate abutment screw. The Multi-unit Abutment Plus is compatible with the Nobel Biocare dental implants that have the internal conical connection.

The Multi-unit Abutment Plus is available for Internal Conical Connection implants with the Narrow Platform (NP), Regular Platform (RP) and Wide Platforms (WP). The Multi-unit Abutment Plus is available with collar heights of 1.5, 2.5, 3.5, and 4.5 mm and angulations of 0°, 17°, 30°.

Snap Temporary Coping Multi-Unit Titanium
The Temporary Snap Coping is a premanufactured dental abutment directly connected to the Multi-unit abutment plus. The temporary coping is co-packed with a prosthetic screw. 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

The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

VI. Comparison of Technological Characteristics

Technological characteristics		Subject Device	Predicate
		Multi-unit Abutment Plus	NobelActive Multi Unit Abutment (K072570)
Design Features	Compatible Implant Platform	Nobel Biocare Internal Conical Connection - Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)	Nobel Biocare Internal Conical Connection - Narrow Platform (NP) - Regular Platform (RP)
	Device Material	Abutments and screws – Titanium vanadium alloy	Abutments and screws – Titanium vanadium alloy
	Abutment collar height	1.5, 2.5, 3.5, 4.5 mm	1.5, 2.5, 3.5, 4.5 mm
	Abutment width	4.8 mm	4.8 mm
	Abutment Angulation	0°, 17°, 30°	0°, 17°, 30°
Intended use		Multi-unit Abutment Plus in combination with endosseous implants are intended for multiple unit reconstructions when screw retained prosthetics is preferred.	Multi-unit Abutment in combination with endosseous implants are intended for multiple unit reconstructions when screw retained prosthetics is preferred.
Indication for Use		The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Analysis of Differences Between Subject Device and Predicate

The Multi-unit Abutment Plus is an evolution of the predicate NobelActive Multi Unit Abutment. It differs from the predicate in the addition of a Wide Platform (WP) abutment (K133731, NobelActive WP, as a reference predicate) and through integration of a snap coping feature. The snap feature, when used with corresponding coping, facilitates try-in by allowing the provisional restoration to be positioned without using screws. Once fitting of the restoration is completed the restoration is secured with prosthetic screws.

Summary:
The documentation submitted in the premarket notification demonstrates that the Multi Unit Plus is substantially equivalent to the predicate device. Differences in technology were evaluated through comparative performance testing.

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 predicate. The sterilization method is Gamma radiation and has been validated in accordance with ANSI/AAMI/ISO 11137. Therefore, no additional testing was required.
    - The Temporary Snap Coping is delivered non-sterile. A sterilization validation was performed to ensure sterility of the subject device when processed by the end user. Sterilization validations were performed using fractionated pre-vacuum and gravity displacement. Sterilization validations were performed with the worst case dental devices.

- Device Packaging
    - The packaging for the subject device is the same as the 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 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 predicate (K072570, Nobel Biocare), 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.

The fatigue limit of the Multi-unit Abutment Plus 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.

VIII. CONCLUSIONS

The Multi-unit Abutment Plus was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the Multi-unit Abutment Plus 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 and non-clinical test data included in this submission, the Multi-unit Abutment Plus has been shown to be substantially equivalent to the NobelActive Multi Unit Abutment (K072570).