DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 22, 2016

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

Re: K161435
Trade/Device Name: Temporary Snap Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 26, 2016
Received: October 27, 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,

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)*
K161435

Device Name
Temporary Snap Abutment

Indications for Use *(Describe)*

The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (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.

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A.4. 510(k) Summary

I. SUBMITTER

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Date Prepared: November 18, 2016

II. DEVICE

Name of Device: Temporary Snap Abutment
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
Plastic Temporary Abutment (K092377)

Reference Predicate
NobelProcera PEEK Abutments (K120954)

Reference Predicate
NobelActive Wide Platform (WP) (K133731)

IV. DEVICE DESCRIPTION

The Temporary Snap Abutments are premanufactured dental implant abutments directly connected to endosseous dental implants and are intended for use as a temporary aid in prosthetic rehabilitation.

The Temporary Snap Abutments are available in engaging and non-engaging connection designs and with collar heights of 1.5 and 3.0 mm. The Temporary Snap Abutments are compatible with the Nobel Biocare dental implants that have the Narrow Platform (NP), Regular Platform (RP) or Wide Platforms (WP) internal conical connection.

V. INDICATIONS FOR USE

The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (180) days.

VI. Comparison of Technological Characteristics

Technological characteristics		Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
		Temporary Snap Abutment	Plastic Temporary Abutment (K092377)	NobelProcera PEEK Abutments (K120954)	NobelActive Wide Platform (WP) (K133731) Temporary Abutment Only
Design Features	Compatible Implant Platform	Nobel Biocare Internal Conical Connection - Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)	Zimmer Dental Tapered Screw Vent - 3.5, 4.5, and 5.7 mm Platform Screw Vent - 3.5, 4.5, and 5.7 mm Platform	Nobel Biocare - Internal Conical Connection (NP, RP) - External Hex (NP, RP, WP) - Internal Tri-lobe (NP, RP, WP)	Nobel Biocare Internal Conical Connection - Wide Platform (WP)
	Device Material	Abutments and screws – Titanium vanadium alloy (ASTM F1472, ASTM F136)	Abutment - PEEK white Screws - Unknown	Abutment – PEEK white and natural color Screws – Titanium vanadium alloy (ASTM F1472, ASTM F136)	Abutments and screws - Titanium vanadium alloy (ASTM F1472, ASTM F136)
	Abutment collar height	1.5, 3.0 mm	1.0, 4.0 mm	1.0, 1.5 mm	1.5, 3.0 mm
	Abutment width	4.0, 4.5, 6.0 mm	4.5, 5.5, 6.5 mm	4.3, 5.0, 6.0 mm	6.0 mm
	Abutment Angulation	No angulation	Straight and angled	No angulation	No angulation
Intended use		Temporary Snap Abutments are endosseous dental implant abutments that are designed for single use as a temporary prosthesis during the healing process while the permanent prosthesis is fabricated.	The Plastic Temporary Abutments are endosseous dental implant abutments that are designed for single use as a temporary prosthesis during the healing process while the permanent prosthesis is fabricated.	The NobelProcera PEEK Abutments are endosseous dental implant abutments that are designed for single use as a temporary prosthesis during the healing process while the permanent prosthesis is fabricated.	TheNobelActive Wide Platform Temporary Abutments are endosseous dental implant abutments that are designed for single use as a temporary prosthesis during the healing process while the permanent prosthesis is fabricated.

Technological characteristics	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	Temporary Snap Abutment	Plastic Temporary Abutment (K092377)	NobelProcera PEEK Abutments (K120954)	NobelActive Wide Platform (WP) (K133731) Temporary Abutment Only
Indication for Use	The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (180) days.	The Plastic Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Plastic Temporary Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Plastic Temporary Abutment is not to exceed one hundred and eighty (180) days.	The Nobel Biocare PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation	Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Analysis of Differences Between Subject Device and Predicate

The Temporary Snap Abutment differs from the predicates through the integration of a snap feature designed to facilitate prosthetic try in. This difference is detailed below. All other technological characteristics of the Temporary Snap Abutment are shared with one or more of the primary and reference predicates.

The Temporary Snap Abutment incorporates a snap feature. The snap feature facilitates try-in by allowing the provisional restoration to be positioned without using screws. Friction between the implant and abutment holds the abutment in position during the try-in process. Once fitting of the restoration is completed the restoration is secured with prosthetic screws. The inclusion of the snap feature on the Temporary Snap Abutment did not necessitate any modifications to the implant connection.

Summary:
The design differences between the subject and predicate devices do not query the substantial equivalence.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:
Since the subject device does not represent a new worst case, data from the predicate device (K133731) was leveraged in the following aspects of the 510(k).

- 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.
- Biocompatibility
    - The subject device is manufactured from titanium vanadium alloy (ASTM F136 and ASTM F1472) using the same manufacturing method as the predicate, has the same intended use, and the same patient contact type and duration. To assess, Cytotoxcity and GC-MS analysis was performed in accordance with EN ISO 10993-1 and confirmed no leachables or no cytotoxic effect detected. No additional testing was required.
- Sterilization
    - Sterilization validations were performed to ensure the sterility of the subject devices when processed by the end user. The sterilization validations were performed using autoclaves with fractionated pre-vacuum and gravity specific air displacement. The sterilizations were performed with worst case dental devices as described in the AAMI TIR12: 2010.

VIII. CONCLUSIONS

The Temporary Snap Abutment was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the Temporary Snap Abutment 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 included in this submission, the Temporary Snap Abutment has been shown to be substantially equivalent to the predicate devices.