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

December 14, 2017

Re: K172854
Trade/Device Name: NobelPerfect Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 19, 2107
Received: September 20, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K172854

Device Name
NobelPerfect Abutments

Indications for Use *(Describe)*

The NobelPerfect Abutments are pre-manufactured prosthetic components directly connected to the endosseous dental implant and are 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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A.4. 510(k) Summary
K172854

I. SUBMITTER

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Date Prepared: December 13, 2017

II. DEVICE

Name of Device: NobelPerfect Abutments
Common or Usual Name: Endosseous Dental Implant Abutment
Classification Name: Endosseous Dental Implant (21 CFR 872.3630)
Regulatory Class: II
Product Code: NHA

III.PREDICATE DEVICE

Primary Predicate
Replace Scalloped Margin Implant System (K021584)

Reference Predicate:
TREFOIL System (K170135)
NobelActive Wide Platform (K133731)

IV. DEVICE DESCRIPTION

The NobelPerfect Abutments are direct replacement abutments for the Replace Scalloped Margin Implant System which was marketed under the trade name NobelPerfect. The NobelPerfect Abutments consist of both healing and definitive abutments. Both abutment types are co-packed with the necessary clinical screw.

The NobelPerfect Abutments are available for the narrow platform (NP), regular platform (RP), and wide platform (WP). The definitive abutments are 12.0 mm height from the base of the abutment and have no angulation. Both the healing and definitive abutments are made of titanium vanadium alloy.

V. INDICATIONS FOR USE

The NobelPerfect Abutments are pre-manufactured prosthetic components directly connected to the endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation.

Comparison of Predicate and NobelPerfect Abutments Indications for Use

Technological characteristics	Subject Device	Predicate (primary)
	NobelPerfect Abutments	Replace Scalloped Margin Implant System (K021584)
Indication for Use[1]	The NobelPerfect Abutments are pre-manufactured prosthetic components directly connected to the endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation.	The Replace™ Scalloped Margin Implant System is an implant with a scalloped coronal margin, designed for single stage or two stage surgical procedures. The Replace™ Scalloped Margin Implant System is intended for use to restore chewing function in edentulous and/or partially edentulous patients.

1 - Note: K021584 does not include a separate indications for use statement for the abutments included in the Replace Scalloped Margin Implant System. Therefore, an abutment specific indications for use statement was created for the subject devices which falls within the intended use of the primary predicate and the indications for restoring chewing function. "

VI. Comparison of Technological Characteristics

Comparison of Predicate and NobelPerfect Abutment Technological Characteristics

Technological characteristics		Subject Device	Predicate (primary)
		NobelPerfect Abutments	Replace Scalloped Margin Implant System (K021584)
Design Features	Compatible Implant Platform	Replace Scalloped Margin Implants (renamed NobelPerfect Implants) - Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)	Replace Scalloped Margin Implants (renamed NobelPerfect Implants) - Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)
	Device Material	Titanium vanadium alloy (ASTM F1472, ASTM F136)	Titanium vanadium alloy (ASTM F1472, ASTM F136)
	Abutment design	Single piece design with scalloped sides and base extension.	Single piece design with scalloped sides

Technological characteristics		Subject Device	Predicate (primary)
		NobelPerfect Abutments	Replace Scalloped Margin Implant System (K021584)
	Abutment height	12.0 mm from base	7.5 mm from base
	Abutment width	NP – 3.39 x 3.035 mm RP – 3.75 x 3.09 mm WP – 4.255 x 3.50 mm	NP – 3.32 x 3.035 mm RP – 3.75 x 3.09 mm WP – 4.255 x 3.5 mm
	Abutment Angulation	No angulation	No angulation

Comparison of Predicate and NobelPerfect Healing Abutment Technological Characteristics

Technological characteristics		Subject Device	Predicate (primary)
		NobelPerfect Abutments	Replace Scalloped Margin Implant System (K021584)
Design Features	Compatible Implant Platform	Replace Scalloped Margin Implants (renamed NobelPerfect Implants) - Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)	Replace Scalloped Margin Implants (renamed NobelPerfect Implants) - Narrow Platform (NP) - Regular Platform (RP) - Wide Platform (WP)
	Device Material	Titanium vanadium alloy (ASTM F1472, ASTM F136)	Delrin – White
	Abutment design	Single piece design with scalloped implant interface and base extension	Single piece design with scalloped implant interface
	Abutment height	NP – 3.86 mm from base RP – 4.51 mm from base WP – 4.28 mm from base	4.95 mm from base
	Abutment diameter (major)	NP – 4.305 mm RP – 5.065 mm WP – 5.775 mm	NP – 4.3 mm RP – 5.08 mm WP – 5.775 mm
	Scallop taper	NP – 0° RP – 4.8° WP – 5.2°	0°

Analysis of Differences Between Subject Device and Predicate

The NobelPerfect Abutments are replacement abutments for the existing NobelPerfect implant system. Both the definitive and healing abutments have been redesigned to include some improvements. The definitive abutments differ from the predicate abutments in that they have a base extension that extends into the implant that is intended to improve abutments stability. The abutments are also longer than the predicate to facilitate more restorative options. The healing abutments are made of titanium alloy instead of Delrin plastic as the predicate is. The RP and WP platform healing abutments have a slight scallop taper whereas the predicate is straight.

Summary:
The design differences between the subject and predicate were evaluated. Differences in technology were evaluated through performance testing.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:
Since the subject device does not represent a new worst case, data from the reference predicate device TREFOIL System (K170135) 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.
- 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, 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 NobelPerfect Abutment was determined using ISO 14801.

VIII. CONCLUSIONS

The NobelPerfect Abutments were evaluated for substantial equivalence using standard testing. In cases where the NobelPerfect Abutments 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 NobelPerfect Abutments have been shown to be substantially equivalent to the Replace Scalloped Margin Implant System (K021584).