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

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

February 28, 2017

Re: K161655
Trade/Device Name: On1 Concept
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 1, 2017
Received: February 2, 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 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,
Mary S. Runner -A

Digitally signed by Mary S. Runner -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -A, 0.9.2342.19200300.100.1.1=1300087950
Date: 2017.02.28 07:57:33 -05'00'

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)*

K161655

Device Name
On1 Concept

Indications for Use *(Describe)*

The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use 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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510(k) Summary

I. SUBMITTER

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Date Prepared: February 27, 2017

II. DEVICE

Name of Device: On1 Concept
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
NobelProcera Angulated Screw Channel Abutment Conical Connection (K132746)

Reference Predicate
NobelActive Wide Platform (WP) (K133731)

IV. DEVICE DESCRIPTION

The On1 Concept is a 2-piece dental implant abutment system. It is intended to be used with the Nobel Biocare dental implants that have the internal conical connection. The On1 Concept features the On1 Base that once placed on the dental implant is not intended to be removed. The top portion of the On1 Clinical Screw incorporates threads to accommodate the On1 Healing Cap and On1

Prosthetic Screw allowing the On1 Clinical Screw to remain in position after placement and securing of the On1 Base.
The On1 Concept system includes a healing cap, temporary abutment and esthetic abutments which all fit onto the On1 Base. The esthetic abutments are available in both titanium alloy and zirconium oxide.

V. INDICATIONS FOR USE

The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.

VI. Comparison of Technological Characteristics

Technological characteristics		Subject Device	Primary Predicate	Reference Predicate
		On1 Concept	NobelProcera Angulated Screw Channel Abutment Conical (K132746)	NobelActive Wide Platform (WP) (K133731)
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)	Nobel Biocare Internal Connection / Internal Hex - Wide Platform (WP)
	Device Material	On1 Base, Temporary Abutment, On1 Healing Cap, Esthetic Abutment Titanium, Clinical Screws and Prosthetic Screws – Titanium vanadium alloy (ASTM F1472, ASTM F136) On1 Esthetic Abutment Zirconia – Y-TZP zirconium oxide (ISO 6872, ISO 13356)	Abutment base and clinical screw – Titanium vanadium alloy (ASTM F1472, ASTM F136) Abutment post – Y-TZP zirconium oxide (ISO 6872, ISO 13356)	Titanium vanadium alloy (ASTM F1472, ASTM F136)
	Abutment Design	2 piece (base placed either at time of implant placement or with final abutment) Abutment shape fixed	2 piece (base placed with final abutment) Abutment shape personalized	Patient Specific Design
	Abutment height	Combined base and post height Temporary Abut – 8.3, 9.0 mm Esthetic Abut Ti – 8.2, 9.0 mm Esthetic Abut Zi – 8.2, 9.0 mm	Not applicable – abutment shape personalized	Not applicable – abutment shape personalized
	Abutment width	At base 4.8, 5.3, 6.5 mm	Not applicable – abutment shape personalized	Not applicable – abutment shape personalized
	Abutment Angulation	No abutment angulation	Variable screw channel and abutment angulation based on personalized design.	Not applicable – abutment shape personalized

Technological characteristics	Subject Device	Primary Predicate	Reference Predicate
	On1 Concept	NobelProcera Angulated Screw Channel Abutment Conical (K132746)	NobelActive Wide Platform (WP) (K133731)
Intended use	The On1™ devices are intended for use in the field of dentistry. They are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function and esthetics. The On1™ esthetic abutments in combination with the On1™ Base on Nobel Biocare Conical Connection endosseous implants are indicated for single-unit cement retained restorations.	Nobel Biocare's NobelProcera ASC Abutment Zirconia is a customized endosseous dental abutment. The abutment attaches directly to the dental implants and provides a platform for restoration. The NobelProcera ASC Abutment Zirconia is designed and made individually to fit the individual requirements for each patient. The NobelProcera ASC Abutment Zirconia is made out of Zirconia and is delivered with a titanium adapter.	Not Applicable – reference predicate to support abutment for use with Wide platform implants.
Indication for Use	The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.	The NobelProcera Angulated Screw Channel Abutment Conical Connection are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	Not Applicable – reference predicate to support abutment for use with Wide platform implants.

Analysis of Differences Between Subject Device and Predicate

The On1 Concept and predicate NobelProcera Angulated Screw Channel Conical Connection (K132746) are both two piece endosseous dental implant abutments intended to fit the Nobel Biocare internal conical connection dental implants.

The On1 Concept base is designed to be placed either when the dental implant is placed or with the final abutment. Once placed on the dental implant the On1 Base is not intended to be removed. The predicate NobelProcera Angulated Screw Channel Conical Connection (K132746) base is intended to adapt the abutment post to the internal conical connection implant and is placed along with the post when the definitive abutment is placed.

The On1 Concept components are all fixed design components. The abutments do not have any angulation built in. The predicate NobelProcera Angulated Screw Channel Conical Connection (K132746) abutments are individually shaped and can be angulated.

Summary:
The design differences between the subject and predicate devices were evaluated through comparative performance testing. The documentation submitted in the premarket notification demonstrates that the On1 Concept is substantially equivalent to the predicate devices.

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 provided sterile 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 sterilization methods for the subject devices provided non-sterile and to be end user sterilized are pre-vacuum and gravity moist heat sterilization and have been validated in accordance with ANSI/AAMI/ISO 17665-1.
- 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 using 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 On1 Concept was determined using the methods described in ISO 14801. 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 On1 Concept was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the On1 Concept 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 On1 Concept has been shown to be substantially equivalent to the NobelProcera Angulated Screw Channel Conical Connection Abutment (K132746).