March 30, 2020

Nobel Biocare AG
Bernice Jim
Regulatory Affairs Manager
Balz Zimmermann-Strasse 7
8302 Kloten, Zurich
SWITZERLAND

Re: K200040
Trade/Device Name: Universal Base Conical Connection (CC)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA PNP
Dated: December 18, 2019
Received: January 13, 2020

Dear Bernice Jim:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200040

Device Name

Universal Base Conical Connection (CC)

Indications for Use *(Describe)*

The Universal Base Conical Connection is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. The Universal Base Conical Connection consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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A.4. 510(K) Summary

I. SUBMITTER

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Date Prepared: March 30, 2020

II. DEVICE

Name of Device: Universal Base Conical Connection (CC)
Common or Usual Name: Endosseous Dental Implant Abutment
Classification Name: Endosseous Dental Implant (21 CFR 872.3630)
Regulatory Class: II
Product Code: NHA
Secondary Code: PNP

III. PREDICATE DEVICE

Primary Predicate
K180899, Nobel Biocare Universal Base Abutment

IV. REFERENCE DEVICE

Reference Device
K151455, 3Shape A/S – 3Shape Abutment Designer Software
K153645, Vita Zahnfabrik H. Rauter GmbH Co – Vita Enamic® Implant Solutions (IS)
K130436, Multilink Hybrid Abutment Cement – Ivoclar Vivadent, Inc.

V. DEVICE DESCRIPTION

The Universal Base Conical Connection is a dental implant abutment intended to be used with the current Nobel Biocare dental implants that have the existing conical connections.

The Universal Base Conical Connection features a fixed upper shape with indexing feature that is intended to serve as the platform for an in-laboratory CAD/CAM system made mesostructure. The fixed upper shape and indexing feature facilitates the use of CAD/CAM systems by providing a known shape that can be imported into the design software, thereby, simplifying the CAD/CAM design process.

The Universal Base Conical Connection is available for the Nobel Biocare Narrow Platform (NP), Regular Platform (RP) and Wide Platform (WP) for external hex. All sizes are available in either 1.5 or 3mm collar heights. The Universal Base Conical Connection is made of titanium vanadium alloy.

The digital workflow requires the use of the following equipment: - Scanner: 3Shape intra oral scanner Trios (3Shape A/S) - Design Software: 3Shape Abutment Designer Software (3Shape A/S) K151455 - Restorative Material: VITA ENAMIC Implant Solutions (IS) (Vita Zahnfabrik H. Rauter GmbH Co) K153645 - Milling Unit: CORiTEC, imes-icore milling unit

The following restorative design specifications is required:

Restorative design specifications for Universal Base CC	
Parameter	Specification
Angle from axis of the implant	20^{O} Max
Wall Thickness Circular	0.8mm min
Wall Thickness Margin	0.275mm min
Post Height	5.2mm min
Maximum Length, width and Height	EM-14 blank 12x14x18mm EM-10 blank 8x10x15mm

VI.INDICATIONS FOR USE

The Universal Base Conical Connection is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. The Universal Base Conical Connection consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

VII. Comparison of Technological Characteristics

Technological characteristics		Subject Device **Universal Base Conical Connection**	Primary Predicate **Universal Base Abutment (K180899)**
Design Features	Compatible Implant Platform	Nobel Biocare Internal Conical Connection Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Nobel Biocare External Hex Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)
	Ti-base Material	Titanium vanadium alloy (ASTM F136)	Titanium vanadium alloy (ASTM F136)
	Mesostructure/ Crown Material	VITA ENAMIC Implant Solutions (IS)(K153645)	VITA ENAMIC Implant Solutions (IS) (K153645)
	Abutment Design	2 piece – VITA ENAMIC IS(K153645) bonded to Universal Base Abutment mounted on to the implant and fixed with a screw	2 piece – VITA ENAMIC IS (K153645) bonded to Universal Base Abutment mounted on to the implant and fixed with a screw
	Abutment Fixation	Screwed	Screwed
	Maximum Abutment Angulation	20°	20°
	Design Workflow	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455
	Manufacturing Workflow	CORiTEC milling unit (imes-icore) Traditional workflow	CORiTEC milling unit (imes-icore) Traditional workflow
	Mechanical Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO14801
Intended Use		The Universal Base Conical Connection are attached to Nobel Biocare dental implants and are intended to support a crown.	The Universal Base Abutments are attached to Nobel Biocare dental implants and are intended to support a crown.

Technological characteristics	Subject Device	Primary Predicate
	Universal Base Conical Connection	**Universal Base Abutment (K180899)**
Indications for Use	The Universal Base Conical Connection is premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Analysis of Differences Between Subject Device and Predicate

The Universal Base Conical Connection and predicate device, Universal Base Abutment are both abutment systems intended to fit the Nobel Biocare dental implants. Both systems consist of a titanium abutment component and a mesostructured composed of VITA ENAMIC Implant Solutions (IS) (K153645) material. Furthermore, both systems feature a screwed abutment fixation which allows for a maximum abutment angulation correction of 20 degrees.

Discussion about the differences between the subject device and predicate is provided below.

Design Feature – Compatible Implant Platform

The subject device differs from the predicate device in the compatible implant platform, the subject device is designed to be compatible with the internal conical connection implants. The predicate device is compatible with the implant connection external hex only. To facilitate the connection with the conical connection implants the lower portion of the universal abutment has been modified and differs from the predicate, these modifications are discussion further below. The post portion of the abutment remains the same as the predicate. All other features of the abutment are the same as the predicate, Universal Base Abutment (K180899).

Differences:

Connection Shape: The subject device has a cone shape which extends into a hexagon shape at the apex of the abutment. The predicate has a hexagon shape at the apex of the abutment. The shape change facilitates the compatibility with the conical connection implant.

Abutment/Implant connection type: For the conical connection, the abutment is the male, the implant is the female connection, for the predicate, the abutment is the female connection and the implant is the male.

Summary:
The design differences between the subject and predicate device do not raise different questions of safety or effectiveness compared to the predicate. Differences in technology were evaluated through performance testing.

VIII. PERFORMANCE DATA

The following performance testing was submitted in this 510(K) to support substantial equivalence:

Mechanical Testing

Worst case dynamic fatigue testing per ISO 14801:"Dentistry — Implants — Dynamic loading test for endosseous dental implants" was performed and demonstrated compliance with the minimum required fatigue properties of the Universal Base Abutment conical connection with a bonded VITA ENAMIC IS mesostructure.

Biocompatibility Testing

The biocompatibility evaluation for the Universal Base Conical Connection was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Chemical Characterization

The Universal Base Conical Connection is categorized as a long term, implant device with tissue bone contact according to ISO 10993-1. The Universal Base Conical Connection is made of titanium vanadium alloy (ASTM F136).

Software Verification and Validation

Validation was completed on the Universal Base Conical Connection with the 3Shape TRIOS Scanner, 3Shape Abutment Designer Software (K155415), CORiTEC imes-icore milling unit workflow. Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the 3Shape Abutment Designer TM Software (K151455). Software verification and validation testing was conducted to demonstrate that

the restrictions prevent design of the mesostructure component outside of design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

Sterilization Validation

The proposed devices are provided non-sterile and intended to be steam sterilized by the end user. Steam sterilization analysis was performed following AAMI-TIR30, ISO 17665-1, and ISO 17665-2.

Packaging

Since the subject device does not represent a new worst case in terms of device packaging and shelf life, data from the predicate was leveraged as follows: 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.

IX. CONCLUSIONS

The Universal Base Conical Connection was evaluated for substantial equivalence using standard and/or comparative testing. In cases were the Universal Base Conical Connection could be demonstrated as not to represent the 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 Universal Base Conical Connection has been shown to be substantially equivalent to the predicate.