Biomet 3i
% Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

December 13, 2017

Re: K173374
Trade/Device Name: TSV™ BellaTek® Encode® Healing Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 26, 2017
Received: October 27, 2017

Dear Linda Schulz:

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)*

K173374

Device Name

TSV™ BellaTek® Encode® Healing Abutments

Indications for Use *(Describe)*

The TSV™ BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.

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.

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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510(k) Summary K173374
Biomet 3i
TSV™ BellaTek® Encode® Healing Abutments

October 26, 2017

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	TSV™ BellaTek® Encode® Healing Abutments
Common Name	Dental Implant Abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate:

K170013	Eztetic™ BellaTek® Encode® Healing Abutments	Biomet 3i

Reference Predicates for Compatibility:

K061410	Zimmer Dental Implant System	Zimmer Dental, Inc.
K133339	Zimmer Dental Tapered Screw-Vent® T Implant, HA Coated Zimmer Dental Tapered Screw-Vent® M Implant, HA Coated	Zimmer Dental, Inc.
K113753	Tapered Screw-Vent® X Implant	Zimmer Dental, Inc.
K132258	Zimmer Dental Trabecular Metal Implant System	Zimmer Dental, Inc.

INDICATIONS FOR USE

The TSV™ BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.

DEVICE DESCRIPTION

The purpose of this submission is to obtain 510(k) premarket clearance for the TSV™ BellaTek® Encode® Healing Abutments compatible with Tapered Screw-Vent®, Screw-Vent® and Trabecular Metal implant systems. Abutments sizing is based on implant platform diameter.

TSV™ BellaTek® Encode® Healing Abutments are designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final prosthesis. They have the added design feature of machined markings for identification when taking an abutment level impression or an intraoral scan/digital impression. The occlusal surface of the device include machined markings that provide information about the mating implant's position and orientation.

The principal of operation and Encode® Coding Scheme of the subject device is the same as the primary predicate device. The pattern of the markings for the subject device is specific to the Tapered Screw-Vent®, Screw-Vent®, and Trabecular Metal implant lines.

Compatible Implant Sizes

Implant System	Implant Diameter (mmD)	Implant Platform (mmD)	Implant Length (mmL)
Tapered Screw -Vent®	3.7	3.5	8, 10, 11.5, 13,16
	4.1	3.5	8, 10, 11.5, 13,16
	4.7	4.5	8, 10, 11.5, 13,16
	6.0	5.7	8, 10, 11.5, 13,16
Screw-Vent®	3.3	3.5	8,10,13,16
	3.7	3.5	8,10,13,16
	4.7	4.5	8,10,13,16
Trabecular Metal™	3.7	3.5	10, 11.5, 13
	4.1	3.5	10, 11.5, 13
	4.7	4.5	10, 11.5, 13
	6.0	5.7	10, 11.5, 13

PERFORMANCE DATA

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included radiation sterilization validation according to ISO 11137-1 and 11137-2, demonstrating a sterility assurance level (SAL) of 10^{-6}, *Limulus* amebocyte lysate (LAL) testing according to AANSI/AAMI ST 72, biological evaluation according to ISO 10993-1 by reference to K170013, demonstrating acceptable biocompatibility, accelerated and real time aging studies by reference to K170013, demonstrating a shelf life of five years, and MR evaluation by reference to K170013. The subject devices are labeled as MR conditional.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Biomet 3i submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device, TSV™ BellaTek® Encode® Healing Abutments, is substantially equivalent in indications and design principles to the legally marketed primary predicate device.

Comparison	**Subject Device**	**Primary Predicate Device**
	TSV™ BellaTek® Encode® Healing Abutments Biomet 3i	K170013 The Eztetic™ BellaTek® Encode® Healing Abutments Biomet 3i
Indications for Use	The TSV™ BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.	The Eztetic™ BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.
Design		
Scanning Identification	Encode® Coding Scheme (Machined Markings)	Encode® Coding Scheme (Machined Markings)
Emergence Profile (mm)	3.8, 5.0, 5.6, 6.0, 6.8	3.8, 5.0
Platform Diameter (mm)	3.5, 4.5, 5.7	2.9
Gingival Height (mm)	3, 5, 7	3, 4, 6, 8
Implant /Abutment Connection	Internal	Internal
Material		
Abutment	Ti-6AI-4V ELI	Ti-6AI-4V ELI
Screw	Ti-6AI-4V ELI	Ti-6AI-4V ELI

The intended use of the subject device as a healing abutment with landmark machined markings for identification is the same as the primary predicate K170013. The Indications for Use statement for the subject device is the same as the primary predicate Eztetic™ BellaTek® Encode® Healing Abutment, K170013, changing only the name.

The principal of operation and basic design of the Encode Coding Scheme of the subject device is the same as the primary predicate device, Eztetic™ BellaTek® Encode® Healing Abutment, K170013. The pattern of the markings for the subject device is specific to the Tapered Screw-Vent, Screw-Vent, and Trabecular Metal implant lines.

All of the subject device components are manufactured from the same material, in the same facilities, using the same manufacturing processes as used for the previously cleared primary predicate device in K170013.

CONCLUSION

The subject device and the primary predicate device have the same intended use, have same technological characteristics, and are made of the same materials. The subject device and predicate devices encompass the same design principals, including the Encode® Coding Scheme. The subject and predicate devices are packaged in the same materials and are to be sterilized using the same methods.

The data included in this submission demonstrate substantial equivalence to the primary predicate device listed above.