December 21, 2021

Biomet 3i LLC
Krupal Patel
Principal Regulatory Specialist
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K212730
Trade/Device Name: BellaTek Encode Emergence Healing Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 19, 2021
Received: November 22, 2021

Dear Krupal Patel:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K212730

Device Name: BellaTek Encode Emergence Healing Abutments

Indications for Use:
The BellaTek Encode Emergence 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.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

BellaTek Encode Emergence Healing Abutments
510(k) Summary
K212730
12/21/2021

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

I. Submitter Information:

Name: Biomet 3i LLC
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Phone: (561) 776-6923
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Contact Person: Krupal Patel
Job Title: Principal Regulatory Specialist
Email: krupal.patel@zimmerbiomet.com

II. Proprietary Trade Name: BellaTek Encode Emergence Healing Abutments

III. Device Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)

IV. Regulatory Class: Class II

V. Product Code: NHA

VI. Predicate Devices:

Primary predicate device:

- TSV BellaTek Encode Healing Abutments (K173374)

Reference device:

- Eztetic BellaTek Encode Healing Abutments (K170013)
- Certain BellaTek Encode Healing Abutments and Certain EP Healing Abutments referenced in Biomet 3i Dental Abutments and Restorative Components (K072642)

VII. Product Description:

The BellaTek Encode Emergence Healing Abutment is a two-piece healing abutment (abutment with a retaining screw) designed to facilitate gingival tissue healing before a final restoration is placed. It consists of an abutment and a retaining screw that are assembled and packaged together and provided sterile. Both components are machined from Titanium Alloy Ti-6Al-4V ELI

(ASTM F136). They are available in pre-defined diameters, emergence profiles and heights to accommodate varying patient anatomies. The shelf life of the TSV BellaTek Encode Healing Abutment is 5 years from the date of manufacture and they are intended for single use only. The device is packaged in a blister tray with Tyvek Lid and sold sterile. The device is sterilized using the gamma irradiation method. The BellaTek Encode Emergence Healing Abutments are color anodized for aesthetic purposes.

VIII. Indications for Use:

The BellaTek Encode Emergence 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.

IX. Summary of the Technological Characteristics:

The BellaTek Encode Emergence 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. Identification and orientation information is captured in the intraoral scan or model scan.

The BellaTek Encode Emergence Healing Abutments consist of three variations differing primarily on the implant connection: TSV BellaTek Encode Emergence Healing Abutments, Eztetic BellaTek Encode Emergence Healing Abutments, and Certain BellaTek Encode Emergence Healing Abutments. The retaining screw is used to secure the abutment to the implant. The subject device seats on the lead-in bevel (TSV and Eztetic) or the seating surface (Certain) of the implant connection. A substantial equivalence comparison of subject and predicate device is provided in Table 1.

The BellaTek Encode Emergence Healing Abutments and retaining screws are color anodized pink for improved aesthetics. The primary predicate device does not have color anodization, however the reference device in K072642 does have color anodization in a manner similar to the subject devices. The landmark pattern on the occlusal surface of the BellaTek Encode Emergence Healing Abutments represents a simplified “code scheme” that achieves same functionality as the predicate device. The BellaTek Encode Emergence Healing Abutments are offered in additional emergence profiles and slightly different abutment heights to accommodate varying patient anatomy as compared to the predicate device. Risk Analysis was conducted in accordance to ISO 14971 to evaluate the effect of the modifications on the subject device. The Biocompatibility evaluation, MRI assessment and Design Validation studies have shown that the device changes, including emergence profile sizes, full color anodization and machined marking designs, do not raise new risks and it concludes that the differences between the predicate and the subject device do not impact the substantial equivalence of the product.

Table 1: Substantial equivalence table

Feature	**Subject Device** BellaTek Encode Emergence Healing Abutment	**Primary Predicate** TSV BellaTek Encode Healing Abutment (K173374)	**Reference Device 1** Eztetic BellaTek Encode Healing Abutment (K170013)	**Reference Device 2** Certain BellaTek Encode Healing Abutment & Certain EP Healing Abutment (K072642)
Intended Use/ Indications for Use	The BellaTek Encode Emergence 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 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.	Biomet 3i Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained. Restorative Components: • Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing. • Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics. • Screw

Feature	**Subject Device** BellaTek Encode Emergence Healing Abutment	**Primary Predicate** TSV BellaTek Encode Healing Abutment (K173374)	**Reference Device 1** Eztetic BellaTek Encode Healing Abutment (K170013)	**Reference Device 2** Certain BellaTek Encode Healing Abutment & Certain EP Healing Abutment (K072642)
				components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.
Operating Principle	The BellaTek Encode Emergence Healing Abutment aids in prosthetic rehabilitation by supporting the surrounding gingival tissue during the healing period. The healing abutment is fixated on the implant using a retaining screw immediately after implant placement in a one-stage surgical protocol. In a two-stage surgical protocol, the healing abutment is fixated on the implant following the bone healing period. The soft tissue is sutured around the healing abutment and the device remains in the mouth until the soft tissue fully develops.	The TSV BellaTek Encode Healing Abutment aids in prosthetic rehabilitation by supporting the surrounding gingival tissue during the healing period. The healing abutment is fixated on the implant using a retaining screw immediately after implant placement in a one-stage surgical protocol. In a two-stage surgical protocol, the healing abutment is fixated on the implant following the bone healing period. The soft tissue is sutured around the healing abutment and the device remains in the mouth until the soft tissue fully develops.	The Eztetic BellaTek Encode Healing Abutment aids in prosthetic rehabilitation by supporting the surrounding gingival tissue during the healing period. The healing abutment is fixated on the implant using a retaining screw immediately after implant placement in a one-stage surgical protocol. In a two-stage surgical protocol, the healing abutment is fixated on the implant following the bone healing period. The soft tissue is sutured around the healing abutment and the device remains in the mouth until the soft tissue fully develops.	The Certain BellaTek Encode Healing Abutment aids in prosthetic rehabilitation by supporting the surrounding gingival tissue during the healing period. The healing abutment is fixated on the implant using a retaining screw immediately after implant placement in a one-stage surgical protocol. In a two-stage surgical protocol, the healing abutment is fixated on the implant following the bone healing period. The soft tissue is sutured around the healing abutment and the device remains in the mouth until the soft tissue fully develops.
Scanning	Encode Coding	Encode Coding	Encode Coding	Encode Coding

Feature	**Subject Device** BellaTek Encode Emergence Healing Abutment	**Primary Predicate** TSV BellaTek Encode Healing Abutment (K173374)	**Reference Device 1** Eztetic BellaTek Encode Healing Abutment (K170013)	**Reference Device 2** Certain BellaTek Encode Healing Abutment & Certain EP Healing Abutment (K072642)
Identification	Scheme (Machined Markings)	Scheme (Machined Markings)	Scheme (Machined Markings)	Scheme (Machined Markings)
Emergence Profile (mm)	**TSV Abutments:** 3.8, 4.5, 5.0, 5.5, 5.7, 6.5, 6.8 and 7.5 **Eztetic Abutments:** 3.7 and 4.5 **Certain Abutments:** 3.8, 4.1, 5.0, 6.0, 6.8 and 7.5	3.8, 5.0, 5.6, 6.0 and 6.8	3.8 and 5.0	3.8, 4.1, 5.0, 5.6, 6.0, 6.8 and 7.5
Abutment Height (mm)	**TSV Abutments:** 3.0, 5.0 and 7.0 **Eztetic Abutments:** 3.0, 5.0 and 7.0 **Certain Abutments:** 3.0, 5.0 and 7.0	3.0, 5.0 and 7.0	3.0, 4.0, 6.0 and 8.0	3.0, 4.0, 6.0 and 8.0
Restorative Platform Diameter (mm)	**TSV Abutments:** 3.5, 4.5 and 5.7 **Eztetic Abutments:** 2.9 **Certain Abutments:** 3.4, 4.1, 5.0 and 6.0	3.5, 4.5. 5.7	2.9	3.4, 4.1, 5.0 and 6.0
Mating Implant	**TSV Abutments:** Zimmer Dental TSV Dental Implant System **Eztetic Abutments:** Zimmer Dental Eztetic Dental Implant System **Certain Abutments:** Biomet 3i Certain (Internal Hex) Dental Implant System	Zimmer Dental TSV Dental Implant System	Zimmer Dental Eztetic Dental Implant System	Biomet 3i Certain (Internal Hex) Dental Implant System
Color Anodization	Pink color anodization	None	None	Certain EP Healing Abutment include color anodized surfaces
Abutment and Screw Material	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy (Ti-6Al-4V ELI)
Packaging	Bubble Tray packaging configuration	Bubble Tray packaging configuration	Bubble Tray packaging configuration	Bubble Tray packaging configuration
Sterilization	Supplied Sterile	Supplied Sterile	Supplied Sterile	Supplied Sterile

Feature	**Subject Device** BellaTek Encode Emergence Healing Abutment	**Primary Predicate** TSV BellaTek Encode Healing Abutment (K173374)	**Reference Device 1** Eztetic BellaTek Encode Healing Abutment (K170013)	**Reference Device 2** Certain BellaTek Encode Healing Abutment & Certain EP Healing Abutment (K072642)
Method	(Gamma radiation)	(Gamma radiation)	(Gamma radiation)	(Gamma radiation)
Shelf Life	5 years	5 years	5 years	5 years
Single Use	Yes	Yes	Yes	Yes

X. Non-Clinical Testing:

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included radiation sterilization validation according to ISO 11137-1 and 11137-2, demonstration a sterility assurance level (SAL) of 10^{-6}, biological evaluation according to ISO 10993-1 demonstrating acceptable biocompatibility and accelerated and real time aging studies by reference to K173374 demonstrating a shelf life of five years.

The subject devices have less surface area and are made out of same materials as compared to previously tested Biomet 3i devices that were used for MR compatibility testing. Hence the MR testing data is leveraged and the subject devices are labeled as MR conditional.

Risk analysis was conducted in accordance to ISO 14971 to evaluate the effect of the modifications on the subject device. The changes in design from the predicate devices have been verified through biocompatibility evaluation, MRI compatibility assessment and design validation study. The changes to the subject device do not identify new risks, nor do the changes impact the risk profile of the device compared to the predicate devices. Revised labeling was provided to ensure proper placement of the device due to differences in emergence profile. Design control activities conclude that the differences between the predicate and the subject device do not impact the substantial equivalence of the product. In addition, confirmatory cytotoxicity testing was performed via ISO 10993-5, which also demonstrated substantial equivalence.

No clinical data were included in this submission.

XI. Conclusion:

The subject devices have demonstrated substantial equivalence to the predicate devices in that they utilize same materials and fundamental designs and also have the same intended use and principles of operation.