



Food and Drug Administration
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BIOMET 3i
Krupal Patel
Senior Regulatory Specialist
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

September 21, 2017

Re: K170013

Trade/Device Name: Eztetic™ BellaTek® Encode® Healing Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 1, 2017
Received: September 5, 2017

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. 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 -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

INDICATIONS FOR USE

510(k) Number (if known): K170013

Device Name: Eztetic™ BellaTek® Encode® Healing Abutments

Indications for Use:

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.

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)

**Eztetic™ BellaTek® Encode® Healing Abutments
510(K) Summary
09/21/2017**

I. Submitter Information:

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II. Proprietary Trade Name: Eztetic™ BellaTek® Encode® 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:

- BellaTek® Encode® Healing Abutments referenced in Biomet 3i Dental Abutments and Restorative Components (K072642 / SE 12/20/2007)

Reference device:

- Healing Collars referenced in Zimmer 3.1mm Dental Implant System (K142082 / SE 07/28/2014)

VII. Product Description:

The Eztetic™ BellaTek® Encode® Healing Abutment is a healing abutment designed to facilitate gingival tissue healing. It consists of an abutment and a retaining screw that are assembled together. Both components are machined from Titanium Alloy (Ti-6AL-4V ELI). The shelf life of the Eztetic™ BellaTek® Encode® Healing Abutment is 5 years and they are intended for single use only. The device is packaged in a sealed nylon bag and sold sterile. The device is sterilized using gamma irradiation method.

VIII. Indications for Use:

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.

IX. Summary of the Technological Characteristics:

The Eztetic™ BellaTek® Encode® Healing Abutments is available in 2.9mm restorative platform diameter, four heights: 3, 4, 6 and 8mm and two emergence profiles: 3.8 and 5mm. The height, emergence profile and the screw method of attachment with mating implant are same as primary predicate devices. The major change from the primary predicate device is the restorative platform diameter. However the restorative platform diameter is same as the reference device. The connection geometry of subject device is similar to reference device and they both engage Eztetic™ 3.1mm Dental Implant. The abutment form a passive or clearance fit within the implant internal connection. The retaining screw is used to secure the abutment to the implant. The abutment makes a flat-on-flat engagement with top surface of the implant platform. A general device comparison of subject and predicate device is provided in table below.

Table 1: General device comparison

Feature	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device</u>
	Eztetic™ BellaTek® Encode® Healing Abutment	BellaTek® Encode® Healing Abutment (K072642)	Healing Collars (K142082)
Intended Use/ Indications for Use	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 to the abutment. Restorative Components: <ul style="list-style-type: none"> • Temporary Healing 	Zimmer 3.1mmD Dental Implants are designed for use in the anterior maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. Zimmer 3.1mmD Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to minimally support the

Feature	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device</u>
	Eztetic™ BellaTek® Encode® Healing Abutment	BellaTek® Encode® Healing Abutment (K072642)	Healing Collars (K142082)
		<p>Abutments are intended for use to shape and maintain the soft tissue opening during healing.</p> <ul style="list-style-type: none"> • Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics. • Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant. 	<p>implant (minimum 1mm circumferential and 2mm apical). The Zimmer 3.1mmD Dental Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.</p> <p>The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are used for attachment of restorations requiring off-axis correction. The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are designed to be used in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.</p> <p>The 2.9mm Contour Abutment and 2.9mm Contour Abutment Straight Hex are used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single- or multiple-unit restoration. The 2.9mm Angled Contour Abutment and 2.9mm Angled Contour Abutment, Straight Hex are designed to be used as a</p>

Feature	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device</u>
	Eztetic™ BellaTek® Encode® Healing Abutment	BellaTek® Encode® Healing Abutment (K072642)	<p>Healing Collars (K142082)</p> <p>terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Abutment can be used for a single-or multiple-unit restoration.</p> <p>The 2.9mm Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The 2.9mm Temporary Abutment can be used for cement-retained or screw-retained provisional restorations. The abutments can be used for single-unit and multiple-unit restorations.</p> <p>The Ball Abutment is used for retaining overdentures or partial dentures when resilience and facilitated oral hygiene are desired.</p> <p>The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed.</p> <p>The Healing Screw is used to seal the implant internal connection and separate it from the soft tissue which is sutured over the implant during healing.</p>

Feature	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device</u>
	Eztetic™ BellaTek® Encode® Healing Abutment	BellaTek® Encode® Healing Abutment (K072642)	Healing Collars (K142082)
Operating Principle	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	The 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 occlusal surface of the device includes machined markings that provide information about the	The Eztetic™ Healing Collar is designed to facilitate gingival tissue healing. The Eztetic™ Healing Collar aids in prosthetic rehabilitation by supporting the surrounding gingival tissue during the healing period. The soft tissue is sutured around the healing collar and the device remains in the mouth until the soft tissue fully develops. The healing collar is threaded onto the implant immediately after implant placement in a one-stage surgical protocol. In a two-stage surgical protocol, the healing collar is threaded on the implant following the bone healing period.

Feature	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device</u>
	Eztetic™ BellaTek® Encode® Healing Abutment	BellaTek® Encode® Healing Abutment (K072642)	Healing Collars (K142082)
	device remains in the mouth until the soft tissue fully develops. The occlusal surface of the device includes machined markings that provide information about the mating implant's position and orientation.	mating implant's position and orientation.	
Technological Characteristics	Encode® Coding Scheme (Machined Markings)	Encode® Coding Scheme (Machined Markings)	No Machined Markings
Method of Attachment (Mating)	Attached to the implant by a retaining screw	Attached to the implant by a retaining screw	Threads into implant
Emergence Profile	3.8mm and 5.0mm	3.8mm - 7.5mm	3.7mm and 4.5mm
Height	3, 4, 6 and 8mm	3, 4, 6 and 8mm	1.5, 3.0 and 4.5mm
Restorative Platform Diameter	2.9mm	3.4, 4.1, 5.0 and 6.0mm	2.9mm
Connection Geometry	Flat-to-flat mating with a passive fit within the implant internal connection to engage Eztetic™ 3.1mm Dental Implant	Flat-to-flat mating with a passive fit within the implant internal connection to engage Biomet 3i External and Internal Hexagon Implants	Flat-to-flat mating with a passive fit within the implant internal connection to engage Eztetic™ 3.1mm Dental Implant
Mating Implant	Zimmer Dental 3.1mm Eztetic™ Implant System	Biomet 3i Internal and External Hexagon Implant System	Zimmer Dental 3.1mm Eztetic™ Implant System
Packaging	Nylon Bag	Nylon Bag	Sealed Tray in an outer chipboard box
Materials	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy (Ti-6Al-4V ELI)

Feature	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device</u>
	Eztetic™ BellaTek® Encode® Healing Abutment	BellaTek® Encode® Healing Abutment (K072642)	Healing Collars (K142082)
Sterilization	Gamma Radiation Method	Gamma Radiation Method	Gamma Radiation Method
Shelf Life	5 years	5 years	5 years
Single Use Only	Yes	Yes	Yes
Components/ Accessories	NA	NA	NA

The Indications for Use for the subject device is specific to the healing abutment, therefore parts of the Indications for use for the predicate and reference devices that refer to the implants and abutments were omitted. The predicate submissions also included implants and abutments that were part of the dental implant system. These devices are not used for comparison since they have different indications for use as compared to subject devices. The primary predicate device is BellaTek® Encode® Healing Abutments referenced in Biomet 3i Dental Abutments and Restorative Components (K072642) and the reference device is Healing Collars referenced in Zimmer 3.1mm Dental Implant System (K142082).

X. Non-Clinical Testing:

The subject devices have less surface area and volume and are made out of identical 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.

Since the subject devices are manufactured out of identical materials and go through the identical manufacturing conditions, solvents and procedures as the primary predicate devices, the biocompatibility data of the primary predicate device was leveraged.

Sterilization is performed in the same manner as primary predicate devices. Sterilization is accomplished using gamma radiation at an exposure dose of 25 to 38 kGy and was validated under a dose setter using VD_{max}^{25} method in accordance with “ISO 11137-2, Sterilization of Health Care Products – Radiation Part 2 – Establishing the sterilization dose”. This validated dose results in a minimum sterility assurance level of 10^{-6} . Sterilization and dose audits are conducted in accordance with “ISO 11137-1, Sterilization of Health Care Products – Radiation Part 1 Requirements for Development, Validation and Routine Control of a sterilization process for medical devices”. Biomet 3i conducts quarterly dose audits for devices that are sterilized using gamma radiation method.

The Eztetic™ BellaTek® Encode® Healing Abutments will maintain an identical five (5) year shelf-life as the primary and secondary predicate devices. Shelf life of the nylon bags used to package the device has been verified by conducting accelerated aging and real-time aging studies of nylon bags in accordance with Biomet 3i quality procedures. Subsequent to the aging studies, shipping and distribution study was also performed per “ASTM D4169 – Standard practice for performance testing of shipping containers and systems” to determine the ability of the product structure to withstand shipping/vibration conditions in the packaging. Upon completion of the shipping and distribution test, the sterile barrier integrity was tested by dye penetration and seal strength methods and it met the acceptance criteria of these tests per “ISO 11607-1: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems”. These tests demonstrated that the product packaging was able to maintain a sterile barrier over the length of its labeled shelf life.

The performance of the subject devices is determined by the material used to manufacture these devices and the structural integrity of the devices over the stated shelf-life. The material used for the subject devices (Ti-6Al-4V-ELI Titanium Alloy) have a shelf life much exceeding 5 years. The Titanium Alloy used to manufacture the subject devices is commonly used in medical devices and is stable at normal storage conditions. Per “ASTM F136: Standard Specification for Wrought Titanium-6 Aluminium-4 Vanadium ELI Alloy”; this alloy composition has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Therefore, a 5 year shelf life for the Eztetic™ BellaTek® Encode® Healing Abutments can be substantiated and the device performance will be maintained for the entirety of the proposed shelf-life.

The changes in design from the primary predicate devices have been verified through bench testing studies. Torque to failure testing was performed on subject devices in the same manner as primary predicate devices in order to demonstrate that the retaining screw can withstand the recommended torque. Physical fit check evaluation was performed on subject devices in the same manner as primary predicate devices in order to assure that the device fits with the mating implant. Tolerance analysis was performed on subject devices in the same manner as primary predicate devices in order to assure that the entire tolerance range meets the design input. Print verification was performed on subject devices in the same manner as primary predicate devices in order to assure that the subject devices are properly constrained and accurately describe the intended original design. These studies have demonstrated that the subject devices are substantially equivalent to predicate devices.

XI. Conclusion:

The subject devices have demonstrated substantial equivalence to the predicate devices in that they have identical intended use, identical operating principle, identical materials and very similar fundamental designs.