December 9, 2019

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

Re: K192522
Trade/Device Name: TSV BellaTek® Express and BellaTek® Flex Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 11, 2019
Received: September 13, 2019

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,

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

INDICATIONS FOR USE

510(k) Number (if known): K192522

Device Name: TSV BellaTek® Express and BellaTek® Flex Abutments

Indications for Use:
TSV BellaTek® Express and BellaTek® Flex Abutments are intended for use as accessories to endosseous dental implants 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.

All digitally designed superstructures and/or hybrid abutment crowns for use with TSV BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.

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)

TSV BellaTek® Express and BellaTek® Flex Abutments
510(k) Summary
K192522
9/December/2019

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
Address: 4555 Riverside Drive
Palm Beach Gardens, Florida 33410
Phone: (561) 776-6923
Fax: (561) 514-6316

Contact Person: Krupal Patel
Job Title: Senior Regulatory Specialist
Email: krupal.patel@zimmerbiomet.com

II. Proprietary Trade Name: TSV BellaTek® Express and BellaTek® Flex Abutments

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

IV. Regulatory Class: Class II

V. Product Code: NHA

VI. Reviewing Branch: Dental Devices Branch

VII. Predicate Devices:

Primary predicate device:
- Certain BellaTek Express and BellaTek Flex Abutment (K183138 / SE 07/02/2019)

Reference Predicate Device:
- Zimmer Zfx Titanium Base Abutment (K133551 / SE 07/18/2014)

VIII. Indications for Use:
TSV BellaTek Express and BellaTek Flex Abutments are intended for use as accessories to endosseous dental implants 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.

All digitally designed superstructures and/or hybrid abutment crowns for use with TSV BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.

IX. Device Description:

The TSV BellaTek Express Abutment and BellaTek Flex Abutment (subject devices) are Titanium-base type abutments to be used as the apical part of two-piece abutments. The coronal part of the two-piece abutment is a CAD/CAM designed and manufactured superstructure. All digitally designed superstructures manufactured in zirconia conform to ISO 13356:2015 and ISO 6872:2015. Biomet 3i recommends the use of Ivoclar Vivadent Multilink Hybrid Abutment Cement (K130436) to affix the zirconia superstructure and/or hybrid abutment crown to the Certain BellaTek Express and BellaTek Flex abutments. TSV BellaTek Express Abutment and BellaTek Flex Abutment are intended to be used with Zimmer Dental's Tapered Screw-Vent, Screw-Vent and Trabecular Metal dental implants for single and multi-unit restorations. The subject device abutments are available in hexed (single-unit) and non-hexed (multi-unit) configurations. They are available in pre-defined platform diameters, emergence profiles and heights to accommodate varying patient anatomies. They are machined from Titanium Alloy. They are intended for single use only. The device is packaged in a sealed nylon bag and sold non-sterile.

The TSV Titanium ASC screw used with the subject device is also machined from Titanium Alloy and anodized pink. The device is packaged individually in a sealed nylon bag and sold sterile. When the TSV BellaTek Express or BellaTek Flex Abutment is placed on the corresponding implant, the retaining screw will mate with the internal thread feature of the dental implant to hold the abutment in place.

Biomet 3i LLC and Zimmer Dental, Inc. have merged under Zimmer Biomet. This 510(k) Premarket Notification is submitted under the entity Biomet 3i LLC. Design and manufacturing parameters including dimensions, tolerances, material specifications, and manufacturing processes have been shared within Zimmer Dental and Biomet 3i LLC to ensure the subject TSV BellaTek Express and BellaTek Flex Abutments are compatible with Zimmer Dental's Tapered Screw-Vent, Screw-Vent and Trabecular Metal implant systems.

X. Summary of the Technological Characteristics:

The subject devices, ***TSV BellaTek Express Abutment and BellaTek Flex Abutment***, are Titanium-base type abutments to be used as the apical part of two-piece abutments. They feature a narrow collar for improved aesthetics, pre-grooved preparation markings for varying occlusal heights, and the screw or cement retained restoration option. Subject device abutments are available in 3.5mm, 4.5mm and 5.7mm platform diameters. A general device comparison of the subject and predicate devices is provided in **Table 1**.

The Indications for Use statement for the subject device is the same as that for the primary predicate device, except for the name of the device.

Certain BellaTek Express and BellaTek Flex Abutments cleared in K183138 are used as a primary predicate device as the design features of these devices are similar to the subject device.

Table 1: General device comparison

Comparison	Subject Device	Primary Predicate Device (K183138)	Reference Predicate Device (K133551)
	TSV BellaTek Express and BellaTek Flex Abutment Biomet 3i	Certain BellaTek Express and BellaTek Flex Abutment Biomet 3i	Zimmer Zfx Titanium Base Abutments for Tapered Screw-Vent Implant System Zimmer Dental
Indications for Use	The TSV BellaTek Express and BellaTek Flex Abutments are intended for use as accessories to endosseous dental implants 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 prostheses, in the mandible or maxilla. The prostheses can be screw retained or cement retained. All digitally designed superstructures and/or hybrid abutment crowns for use with TSV BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.	The Certain BellaTek Express and BellaTek Flex Abutments are intended for use as accessories to endosseous dental implants 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 prostheses, in the mandible or maxilla. The prostheses can be screw retained or cement retained. All digitally designed superstructures and/or hybrid abutment crowns for use with Certain BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.	The Zimmer Zfx Titanium Base Abutment is a combination of a pre-manufactured (stock) abutment and the Zimmer Zfx Abutment Coping or Crown as part of a straight or angled two- piece abutment. The combination of the titanium base stock abutment and the abutment coping is designed for use as a terminal or intermediate abutment for cement or screw retained prostheses. The two-piece abutment is used for a single-unit or multi-unit (bridge) restoration. The Zimmer Zfx Abutment Coping shall be manufactured by an approved Zimmer Dental milling facility.
Intended Use	It is a device, which attaches to the dental implant to restore chewing function.	It is a device, which attaches to the dental implant to restore chewing function.	It is a device, which attaches to the dental implant to restore chewing function.
Platform Diameter	3.5mm, 4.5mm and 5.7mm	3.4mm, 4.1mm, 5.0mm and 6.0mm	3.5mm, 4.5mm and 5.7mm
Abutment	4.75 and 12mm	4.75 and 12mm	3.9mm

Comparison	Subject Device	Primary Predicate Device (K183138)	Reference Predicate Device (K133551)
	TSV BellaTek Express and BellaTek Flex Abutment Biomet 3i	Certain BellaTek Express and BellaTek Flex Abutment Biomet 3i	Zimmer Zfx Titanium Base Abutments for Tapered Screw-Vent Implant System Zimmer Dental
Height			
Abutment Angle	Straight	Straight	Straight
Implant /Abutment Connection	Zimmer Dental's Tapered Screw-Vent, Screw-Vent and Trabecular Metal Implants	Biomet 3i Internal Hex Implants	Zimmer Dental's Tapered Screw-Vent and Screw-Vent Implant System
Restoration	Single unit & Multi unit	Single unit & Multi unit	Single unit & Multi unit
Prosthesis Attachment	Screw or Cement retained	Screw or Cement retained	Screw or Cement retained
Abutment	Titanium Alloy (Ti-6Al-4V ELI) and Zirconia	Titanium Alloy (Ti-6Al-4V ELI) and Zirconia	Titanium Alloy (Ti-6Al-4V ELI)
Retaining Screw	Titanium Alloy (Ti-6Al-4V ELI)	Stainless Steel 316L, Gold Alloy or Palladium Alloy	Titanium Alloy (Ti-6Al-4V ELI)

TSV BellaTek Express and BellaTek Flex Abutments are substantially equivalent in design, function, material, and Indications for Use to Certain BellaTek Express and BellaTek Flex Abutments (K183138). They are intended for use with endosseous dental implants in the maxilla and mandible to provide prosthetic support. All digitally designed superstructures for use with the subject device and the primary predicate device are to be sent to a validated milling center for manufacture. The subject device and the reference predicate device (K133551) has same platform diameters. They are available in 3.5mm, 4.5mm and 5.7mm platform diameters compatible with the corresponding Zimmer Dental implants.

XI. Performance Data:

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included steam sterilization validation according to *ISO 17665-1* and gamma sterilization validation according to *ISO 11137-1* and *ISO 11137-2*, demonstrating a sterility assurance level (SAL) of 10^{-6}, biological evaluation according to *ISO 10993-1* demonstrating acceptable biocompatibility by reference to K183138, and Magnetic Resonance testing showing the device as MR conditional by reference to K150571.

Aging/Shelf-Life is not applicable to the subject device abutment, TSV BellaTek Express and BellaTek Flex Abutment, as it is supplied non-sterile.

The retaining screw, TSV Titanium Angled Screw Channel Screw, used with the subject device abutment is packaged in the same packaging system (Nylon Bag) as the retaining screw, Certain Gold-Tite Hexed UniScrew that is used with the predicate device abutment and will maintain an identical 5-year shelf-life. 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 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. 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.

Devices were designed & developed in accordance to following applicable FDA Guidance Document:

1) Guidance for Industry and FDA staff – *Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*
2) Guidance for Industry and FDA staff – *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*
3) Guidance for Industry and FDA staff - *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*
4) Guidance for Industry and FDA staff – *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*.

No clinical data was included in this submission.

XII. Conclusion:

The subject device has demonstrated substantial equivalence to the predicate devices in that it has the same intended use, the same operating principle, identical materials and similar fundamental design.