July 2, 2019

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

Re: K183138
Trade/Device Name: Certain 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: June 5, 2019
Received: June 7, 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.
Acting Assistant 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): K183138

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

Indications for Use:
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 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 Certain 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)

Certain BellaTek® Express and BellaTek® Flex Abutments
510(k) Summary
K183138
2/July/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
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: Certain 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:

- GingiHue Abutments and Temporary Cylinders referenced in Biomet 3i Dental Abutments and Restorative Components (K072642 / SE 12/20/2007)

Reference predicate device:

- Titanium-base Abutments referenced in Terrats Medical SL's DESS Dental Smart Solutions (K170588 / SE 08/08/2017)

VIII. Indications for Use:

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 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 Certain BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.

IX. Device Description:

The Certain 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. Certain BellaTek Express Abutment and BellaTek Flex Abutment are intended to be used with Biomet 3i Certain (Internal Hex) 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.

X. Summary of the Technological Characteristics:

The subject devices, ***Certain 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 3.4, 4.1, 5.0 and 6.0mm 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 similar to the Indications for Use statement for the Primary Predicate Device.

GingiHue Abutments and Temporary Cylinders cleared in K072642 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	Reference Predicate device
	Certain BellaTek Express and BellaTek Flex Abutments **Biomet 3i**	**K072642** Biomet 3i Dental Abutments & Restorative Components **Biomet 3i**	**K170588** DESS Dental Smart Solutions **Terrats Medical SL**
Indications for Use	Certain BellaTek Express and BellaTek Flex	Biomet 3i Dental Abutments are intended for use as	DESS Dental Smart Solutions abutments

Comparison	Subject Device	Primary Predicate Device	Reference Predicate device
	Certain BellaTek Express and BellaTek Flex Abutments **Biomet 3i**	**K072642** Biomet 3i Dental Abutments & Restorative Components **Biomet 3i**	**K170588** DESS Dental Smart Solutions **Terrats Medical SL**
	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. All digitally designed superstructure and/or hybrid abutment crowns for use with Certain BellaTek Express and BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.	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 prosthesis • Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant	are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with TiBase or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.
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.
Design			
Platform Diameter	3.4, 4.1, 5.0 and 6.0mm	3.4, 4.1, 5.0 and 6.0mm	3.4 – 5.7mm
Abutment Angle	Straight	Straight to 30^0	Straight
Prosthesis Attachment	Screw or Cement retained	Screw or Cement retained	Screw or Cement retained
Restoration	Single unit & Multi unit	Single unit & Multi unit	Single unit & Multi unit
Implant /Abutment Connection	Biomet 3i Internal Hex Implants	Biomet 3i Internal and External Hex Implants	Biomet 3i, Nobel Biocare, Astra Tech, Zimmer Dental,

Comparison	Subject Device	Primary Predicate Device	Reference Predicate device
	Certain BellaTek Express and BellaTek Flex Abutments **Biomet 3i**	**K072642** Biomet 3i Dental Abutments & Restorative Components **Biomet 3i**	**K170588** DESS Dental Smart Solutions **Terrats Medical SL**
			Straumann & Dentsply Implants
Material			
Abutment	Titanium Alloy (Ti-6Al-4V ELI) and Zirconia	Titanium Alloy (Ti-6Al-4V ELI) & Commercial Pure Titanium	Titanium Alloy (Ti-6Al-4V ELI)

Certain BellaTek Express and BellaTek Flex abutments are substantially equivalent in design, function, material, and Indications for Use to GingiHue Abutments & Titanium Temporary Cylinders referenced in Biomet 3i's Dental Abutments (K072642) and Titanium-base abutments referenced in Terrats Medical SL's Dess Dental Smart Solutions (K170588). All 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 reference device are to be sent to a validated milling center for manufacture.

XI. Performance Data:

Non-clinical testing was conducted per FDA Guidance Document (*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*) and steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10^{-6} of the device. Biological evaluation was conducted in accordance with FDA Guidance Document (*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*) demonstrating acceptable biocompatibility of the device. MR testing data is leveraged and the subject device is labeled as MR conditional. Devices were designed & developed in accordance to applicable FDA Guidance Document (*Guidance for Industry and FDA staff – Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*).

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.