



July 15, 2024

Biomet 3i, LLC
% Michael Davis
Principal Consultant
Michael Davis Quality and Regulatory Consulting, LLC
204 Norwick Forest Drive
Alabaster, Alabama 35007

Re: K241032
Trade/Device Name: BellaTek® Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 15, 2024
Received: April 16, 2024

Dear Michael Davis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K241032

Device Name

BellaTek Bars

Indications for Use (Describe)

The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.

All digitally designed BellaTek Bars are intended to be sent to Biomet 3i for manufacture.

The BellaTek Bars are indicated for compatibility with the following abutment systems:

- Universal Multi-Unit Abutments manufactured by Terrats Medical SL., 2.9-5.7mm, Angled, max 30 degrees
 - ZimVie Eztetic Implant System
 - ZimVie TSX Implant System
 - ZimVie Tapered Screw-Vent System
- ZimVie Low Profile Abutments, 3.4-6.0mm, Angled, max 30 degrees
 - ZimVie Osseotite Implant System
 - ZimVie T3 and T3 PRO Implant System
- ZimVie Tapered Abutments, 3.5-5.7mm, Angled, max 30 degrees
 - ZimVie TSX Implant System
 - ZimVie Tapered Screw-Vent Implant System

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)

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BellaTek® Bars
510(k) Summary
21 CFR 807.92
07/15/2024

Submitter's Name & Address

Manufacturer: Biomet 3i, LLC
 4555 Riverside Drive
 Palm Beach Gardens, FL 33410
 Phone (561) 776-6700

Official contact: Krupal Patel
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Name of the Device

Trade Name: BellaTek® Bars
 Common or Usual Name: Dental implant abutment
 Classification Name: Endosseous dental implant abutment
 Classification Number: Class II (21 CFR 872.3630)
 Primary Product Code: NHA

Predicate Devices

Primary Predicate Device: K233083, Osteon Precision Milled Suprastructure, March 9, 2024

Reference Predicate Device: K080864, Biomet 3i CAM StructSURE® Precision Milled Bars, July 21, 2008
 K180998, BioHorizons CAD/CAM Bars, September 28, 2018
 K231434, Terrats Medical Dental Smart Solutions Abutments, August 14, 2023
 K092341, Biomet 3i Low Profile Abutments – Internal and External Connection, November 30, 2009
 K111853, Zimmer Dental Angled Tapered Abutments, December 8, 2011

Device Description

The BellaTek Bars are intended to disperse the load of a prosthesis across dental implant-abutment assemblies. They also provide support for prosthetic devices such as artificial teeth, and to restore the patient's chewing function. The subject devices are identical to the reference predicate device CAM StructSURE Precision Milled Bars cleared in K080864 (SE 07/21/2008) with the only addition of the new connection geometry. The subject device has a new bar-to-abutment connection tailored to the multi-unit restorative abutment component(s) with which the device is intended to be used. Similar to the primary predicate device (K233083), the BellaTek Bars are manufactured out of commercially pure titanium per ASTM F67 or Titanium Alloy per ASTM F136. The BellaTek Bars are placed in a nylon bag and sealed in same manner as the reference predicate device (K080864). A label is applied to the bag.

Like the primary predicate device (K233083), the BellaTek Bars are offered in two types. A Type I Bar is a Titanium Alloy bar designed for use with removable overdentures. A Type II Bar is a Pure Titanium or Titanium Alloy bar designed for fixed prosthesis. All BellaTek Bars (Dolder, Primary, Hader, Hybrid, Freeform, Canada, Wraparound and Copy Milled) are designed to match an individual

patient. The bars are designed from a three-dimensional optical and/or digital scanner system that scans the casting of a patient's impression and then is machined using a CAD/CAM software system in accordance with customer specifications, within the limits of design defined in tables below. The subject devices are provided non-sterile in same manner as the predicate devices. Below are the design matrix specifications that serve as instructions and limitations for the design of each bar. The design specifications for the subject BellaTek Bars included in the tables below are identical to the reference predicate CAM StructSURE Precision Milled Bars.

Table 1: Type I Bars: Removable

Description	Minimum	Maximum
Platform Seating Diameter	3.4mm	6.1mm
Total Cylinders	2	10
Bar Span Between Cylinders	0mm	27mm
Bar Height	2.5mm	10mm
Bar Width	1.8mm	10mm
Distal Extension	0mm	10.7mm
Cylinder Height	0mm	10mm
Cylinder Diameter	3.4mm	10mm
Maximum Angulation Between Cylinders	0°	30°

Table 2: Type II Bars: Fixed

Description	Minimum	Maximum
Platform Seating Diameter	3.4mm	6.1mm
Total Cylinders	2	10
Bar Span Between Cylinders	0mm	23.5mm
Bar Height	2.5mm	22mm
Bar Width	4.0mm	10mm
Distal Extension	0mm	18mm
Cylinder Height	0mm	19.5mm
Cylinder Diameter	3.4mm	10mm
Maximum Angulation Between Cylinders	0°	30°

The BellaTek Bars are provided with an abutment-level connection interface. The BellaTek Bars include passive, non-indexing connection geometry with seating on the restorative platform of the multi-unit abutment as well as incorporate a screw seat that allows passage through and fixation with a Universal Multi-Unit prosthetic screw. Combined with intaglio-side connection geometry, the prosthetic screw secures the device to the underlying multi-unit abutment. Additionally, the occlusal surface of the BellaTek Bars may include connection geometry (e.g. female threads) to accept overdenture attachments.

Indications for Use

The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.

All digitally designed BellaTek Bars are intended to be sent to Biomet 3i for manufacture.

The BellaTek Bars are indicated for compatibility with the following abutment systems:

- Universal Multi-Unit Abutments manufactured by Terrats Medical SL., 2.9-5.7mm, Angled, max 30°
 - ZimVie Eztetic Implant System
 - ZimVie TSX Implant System
 - ZimVie Tapered Screw-Vent System

- ZimVie Low Profile Abutments, 3.4-6.0mm, Angled, max 30⁰
 - ZimVie Osseotite Implant System
 - ZimVie T3 and T3 PRO Implant System
- ZimVie Tapered Abutments, 3.5-5.7mm, Angled, max 30⁰
 - ZimVie TSX Implant System
 - ZimVie Tapered Screw-Vent Implant System

Summary of the Technological Characteristics

The fundamental scientific technology of the BellaTek Bars that are the subject of this 510(k) is substantially equivalent to the primary predicate device (K233083). Both the subject device and reference predicate device (K080864) include similar features such as bar base material, bar-to-abutment connection tailored to the multi-unit restorative abutment component(s) with which the device is intended to be used, prosthetic platform sizes and mode of prosthetic retention which thereby demonstrates substantial equivalence in their respective designs. Any specific differences related to prosthetic platform connection geometry are supported by the identified predicate devices. The subject device is substantially equivalent to the primary predicate device in intended use, design principles and technological characteristics. The features, base materials, similarities and differences are further summarized in tabular format in the Summary Table of Substantial Equivalence following in this section. The Indications for Use statement for the subject device is substantially equivalent to that of the primary predicate device, except for the list of identified compatible abutment systems. The reference predicate devices (K231434, K092341 and K111853) are included for the purpose of identifying OEM abutment compatibility.

Table 3. Summary Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Predicate Device(s)	
	Biomet 3i BellaTek Bars K241032	Osteon Precision Milled Suprastructure K233083	Biomet 3i CAM StructSURE® Precision Milled Bars K080864	BioHorizons Implant Systems, Inc. CAD/CAM Bars K180998
Intended Use	<p>The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.</p> <p>All digitally designed BellaTek Bars are intended to be sent to Biomet 3i for manufacture.</p> <p>The BellaTek Bars are indicated for compatibility with the following abutment systems:</p> <ul style="list-style-type: none"> • Universal Multi-Unit Abutments manufactured by Terrats Medical SL., 2.9-5.7mm, Angled, max 30⁰ • ZimVie Eztetic Implant System 	<p>The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments.</p> <p>The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems:</p> <ul style="list-style-type: none"> • Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30⁰ • BioHorizons Multi Unit Abutment, 4.8mm, max 30⁰ <ul style="list-style-type: none"> • CONELOG® Implant System • Biomet 3i Multi Unit Abutments, 4.8mm, max 30⁰ • TSX™ Implants 	<p>The CAM StructSURE Precision Milled Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.</p>	<p>BioHorizons CAD/CAM Bars are intended for use as superstructures of a multiple-unit endosseous dental implant system, attaching directly to implants or abutments in the mandible or maxilla, to support a prosthetic device in a partially or fully edentulous patient for the purpose of restoring chewing function. Implant-level bars are compatible with all BioHorizons Internal and Tapered Internal implant systems. Implant-level bars are compatible with Zimmer Dental Screw-Vent® and Tapered Screw Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex connection mating platform diameters and are intended to be used with straight bar cylinders only.</p>

	<ul style="list-style-type: none"> • ZimVie TSX Implant System • ZimVie Tapered Screw-Vent System • ZimVie Low Profile Abutments, 3.4-6.0mm, Angled, max 30° • ZimVie Osseotite Implant System • ZimVie T3 and T3 PRO Implant System • ZimVie Tapered Abutments, 3.5-5.7mm, Angled, max 30° • ZimVie TSX Implant System • ZimVie Tapered Screw-Vent Implant System 	<ul style="list-style-type: none"> • Tapered Screw-Vent Implant • DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0° <ul style="list-style-type: none"> • 3i OSSEOTITE® • Astra Tech OsseoSpeed™ • Neodent Grand Morse • NobelReplace® Trilobe • NobelReplace® Conical • Nobel Brånemark System® • Straumann BLX Implants • DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30° <ul style="list-style-type: none"> • NobelActive® • NobelParallel Conical • Straumann® Bone Level • Zimmer Screw Vent® and Tapered Screw-Vent® • Dentium SuperLine® Abutments, 4.5-5.5 mm, max30° • GENESIS ACTIVE™ Multi-Unit Abutments, 4.8mm, max 30° • Implant Direct GPS® Angled Abutment, 5.0mm, max 30° • KDG Abutments, 4.8mm, max 30° • Keystone Multi Unit Abutment, 4.8mm, 0° • Medentika Multi Unit Abutments, 4.8mm, max 30° <ul style="list-style-type: none"> • EV Series – Dentsply® Implants Astratech Osseospeed® • F Series – Nobel Biocare NobelActive® – NobelReplace® Conical • H Series – Biomet 3i Certain® • L Series – Straumann Bone Level • N Series – Straumann Soft tissue Level • R Series – Zimmer Dental Tapered Screwvent® • Medentika Multi Unit Abutments, 4.8mm, 0° <ul style="list-style-type: none"> • E Series – Nobel Biocare Replace™ Select • I Series – Biomet 3i Osseotite® • K Series – Nobel Biocare™ Branemark • S Series – Astra Tech OsseoSpeed™ • T Series – Dentsply Friadent® Frialit/Xive® • MegaGen Multi Unit 		<p>Abutment-level bars are compatible with BioHorizons Multi-unit Abutments. All digitally designed BioHorizons CAD/CAM Bars are intended to be sent to a BioHorizons-validated milling center for manufacture.</p>
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		<p>Abutments, 4.8mm, max 30°</p> <ul style="list-style-type: none"> • Xpeed® AnyRidge® Internal Implant System • AnyOne® Internal Implant System • AnyRidge® Octa 1 Implant System • AnyOne® External Implant System • AnyRidge® Octa 1 Implant System • AnyOne® Internal Implant System • Rescue Internal Implant System <p>• MIS Multi-unit</p> <p>Abutments, 4.8mm</p> <ul style="list-style-type: none"> • C1 Conical Connection Implant System, max 30° • V3 Conical Connection Implant System, max 30° • Internal Hex Implant System, max 30° • Conical Connection, max 30° <ul style="list-style-type: none"> • Neodent GM Mini Conical Abutment, 4.8 mm, max 30° • Nobel Biocare™ Brånemark Multi Unit Abutment, 4.8 mm, max 17° • Nobel Biocare™ Multi Unit Abutment Plus, 4.8 mm, max 30° • Nobel Biocare™ Multi Unit Abutment, 4.8 mm, max 30° • Nobel Biocare™ Multi Unit Abutments for Straumann and Astra Tech System, 4.8 mm, max 30° • Nobel Biocare™ Multi Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, 4.8 mm, max 30° • Nobel Biocare Xeal Abutments, 4.8 mm, max 30° • OSSTEM Multi Unit Abutment, 4.8mm, max 30° • SS SA Fixture Implants • SA Implant System • ET US SSS Prosthetic System • Paltop Multi Unit Abutment, 5.0 mm, max 17° • Southern Compact Conical Abutments, 4.8 mm • MAX Implant System, 0° • Provata Implant System, max 30° • Deep Conical (DC) 		
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		<ul style="list-style-type: none"> Implants, 0° • Piccolo Implants, 0° • External Hex Implants, max 30° • Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30° • Straumann® Screw Retained Abutment, 4.6 mm, max 30° • Zimmer Angled Tapered Abutments, 4.5 mm, max 30° 		
Design				
Bar shape	Type I (Dolder, Hader, Primary) Type II (Hybrid, Wrap around, Freeform, Canada, CopyMilled)	Type A (for Removable Prosthesis) Type B (for Fixed Prosthesis)	Type I (Dolder, Hader, Primary) Type II (Combination Primary, Hybrid, Wrap around, Freeform, Canada, CopyMilled)	Fixed shape (Dolder®, Hader, Round) Freeform shape (Freeform/Milled, Hybrid, Montreal, Paris, Wrap Around)
Platform seating diameter	3.4mm – 6.1mm	4.5mm – 8.0mm	3.4mm – 6.1mm	3.0mm, 3.5mm, 4.5mm, 5.7mm
Min. number of cylinders	2	2	2	2
Max. anterior-posterior spread	40mm	Not specified	40mm	Not specified
Max. implant span	27mm (Type I) 23.5mm (Type II)	30mm (Type A and Type B)	27mm (Type I) 23.5mm (Type II)	30mm
Mode of retention	Screw-retained	Screw-retained	Screw-retained	Screw-retained
Mating components	Multi-unit Abutments manufactured by Terrats Medical SL	Straight, angled and multi-unit abutments manufactured by various Original Equipment Manufacturers	Multi-unit Abutments manufactured by Biomet 3i LLC	Multi-unit Abutments manufactured by BioHorizons Implant Systems Inc.
Material and Manufacturing				
Bar material	Ti-6Al-4V ELI (ASTM F136) or Grade 4 CP Titanium (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136) or Grade 4 CP Titanium (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)
Packaging	Nylon pouch	Not specified	Nylon pouch	Poly/Tyvek pouch
Sterilization	Moist heat	End-user (methodology not specified)	Moist heat	Moist heat

The Subject Device worst case design was validated with performance bench testing in accordance with Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004, and the differences noted or otherwise not accounted for by comparison to the predicate device are demonstrated by the performance bench testing, and do not render the Subject Device not substantially equivalent.

Summary of Testing

The BellaTek Bars are provided non-sterile. Sterilization by the end user is achieved using one of the validated steam sterilization cycles as specified in the Instructions for Use. Sterilization cycles were validated in accordance with EN ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*, demonstrating a sterility assurance level (SAL) of 10^{-6} of the device.

Finally, the BellaTek Bars meet the chemical and mechanical requirements of ASTM F136 and ASTM F67. These grades of Titanium are commonly used in surgical implant applications. Biocompatibility testing conducted on representative Biomet 3i patient-specific bar devices that used the same ASTM F136 titanium alloy and ASTM F67 unalloyed titanium materials was performed in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*. These tests concluded that the material, chemical testing and literature reviewed provides sufficient basis for demonstrating the biocompatibility of titanium materials for their intended use in the subject devices.

Non-clinical worst-case MRI review was performed to evaluate the BellaTek Bar devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." *Journal of Testing and Evaluation* 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. The rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque. The BellaTek Bars have been labeled as MR conditional.

No clinical data were included in this submission.

Conclusion

The data presented in this submission demonstrates that the proposed devices are substantially equivalent with respect to performance and intended use. Non-clinical testing performed demonstrates that the proposed devices perform as well as the legally marketed predicate devices. Furthermore, the proposed devices do not pose any new or increased risks as compared to the legally marketed predicate devices.