March 1, 2024

GmbH - a company of ZimVie
Ana Leitão
Regulatory & Compliance Senior Specialist
Kopernikusstraße 15
Dachau, 85221
GERMANY

Re: K231915
Trade/Device Name: Zfx Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 31, 2024
Received: February 5, 2024

Dear Ana Leitão:

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,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231915

Device Name
Zfx Abutments

Indications for Use *(Describe)*
The Zfx Abutments 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 or superstructures and/or hybrid abutment crowns for use with Zfx TiBase or Pre-Milled Blank Abutments are intended to be sent to a Zfx validated milling center for manufacture.

Table 1 Compatible Implant Systems

Compatible Implant	Platform Ø (mm)
Certain (Tapered and Parallel Walled), T3, T3 Pro	3.4
	4.1
	5.0
	6.0
Tapered Screw-Vent, Trabecular Metal	3.5
	4.5
	5.7
TSX	2.9
	3.5
	4.5
Eztetic	2.9

The Zfx TiBase abutments for the Ø3.25 mm Certain implant bodies, and Ø3.1 mm Eztetic implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Zfx Abutments
510(k) Summary
March 1st, 2024
[510(k) Number K231915]

Administrative Information

Manufacturer Name	Zfx GmbH Kopernikusstraße 15, 85221 Dachau, Germany
Telephone	+49 162 3088254
Official Contact	Ana Leitão, Regulatory & Compliance Senior Specialist Email: ana.leitao@zimvie.com

Device Name and Classification

Trade/Proprietary Name	Zfx Abutments
Common Name	Dental Implant Abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous Dental Implant Abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Division	Division of Dental Devices

Predicate Device Information

Primary Predicate Device

K222288, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices

K052648, Modification 3i Patient-Specific Dental Abutment and Overdenture Bar, 3i Implant Innovations, Inc.
K100993, Inclusive Titanium Abutments for Astra OsseoSpeed, Prismatik Dental Craft Inc.
K213672, T3 Pro Implants, Biomet 3i LLC
K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent
K092341, Biomet 3i Low Profile Abutments
K063341, 3i OSSEOTITE Certain(R) Dental Implants, Implant Innovations, Inc.
K061629, CERTAIN PREVAIL DENTAL IMPLANT, Implant Innovations, Inc.
K063286, OSSEOTITE; OSSEOTITE NT; XP; TG OSSEOTITE, Implant Innovations, Inc.
K100724, OSSEOTITE II MODEL XIFOSSXXX, Biomet 3i LLC
K111216, OSSEOTITE 2 DENTAL IMPLANTS, Biomet 3i LLC
K130949, CP4 OSSEOTITE CERTAIN DENTAL IMPLANTS, Biomet 3i LLC
K142082, Zimmer 3.1mm Dental Implant [Eztetic], Zimmer Dental, Inc.
K133339, Tapered Screw Vent T & M Implants, Zimmer Dental, Inc.
K113753, Tapered Screw-Vent(R) X Implant, Zimmer Dental, Inc.
K132258, Trabecular Metal Implant, Zimmer Dental, Inc.
K122300, 3i T3 Dental Implant, Biomet 3i LLC

K220978, TSX Implants, Biomet 3i LLC
K212730, BellaTek Encode Emergence Healing Abutments, Biomet 3i LLC

Indications for Use Statement
The Zfx Abutments 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 or superstructures and/or hybrid abutment crowns for use with Zfx TiBase or Pre-Milled Blank Abutments are intended to be sent to a Zfx validated milling center for manufacture.

Table 1 Compatible Implant Systems

Compatible Implant	Platform Ø (mm)
Certain (Tapered and Parallel Walled), T3, T3 Pro	3.4
	4.1
	5.0
	6.0
Tapered Screw-Vent, Trabecular Metal	3.5
	4.5
	5.7
TSX	2.9
	3.5
	4.5
Eztetic	2.9

The Zfx TiBase abutments for the Ø3.25 mm Certain implant bodies, and Ø3.1 mm Eztetic implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Subject Device Description
The subject device, Zfx Abutments, consists of two abutment types, a TiBase and a Pre-milled Abutment Blank, with corresponding retaining screws. Zfx Abutments are offered in a variety of connections compatible with ZimVie dental implants. All abutments and screws are provided non-sterile.

TiBase Abutments
Subject device TiBases are two-piece abutments. The pre-manufactured titanium base component is the apical part. The coronal part of the two-piece abutment is a CAD/CAM designed and manufactured superstructure. The subject device TiBase abutments are available in hexed/engaging and non-hexed/non-engaging configurations. The engaging TiBase abutments are intended for single and multi-unit restorations and the non-engaging TiBases are intended for multi-unit restorations.

The superstructure is intended to be manufactured at a Zfx validated milling center. Zfx recommends the use of Ivoclar Vivadent Multilink Hybrid Abutment Cement

Design parameters for the TiBase CAD/CAM zirconia superstructure are listed in the following tables:

Table 2 Design parameters for manufacturing zirconia superstructure and/or hybrid crowns compatible with Certain (Tapered and Parallel Walled), T3, T3 Pro implant systems

DESIGN PARAMETERS FOR MANUFACTURING ZIRCONIA SUPERSTRUCTURES COMPATIBLE WITH CERTAIN IMPLANT SYSTEMS			
Superstructure Parameters		**Superstructure Parameter Values**	
		Min.	**Max.**
Superstucture Gingival Height (A)	0.3mm TiBase Collar Height	0.25mm	5.75mm
	1.3mm TiBase Collar Height		4.7mm
	2.6mm TiBase Collar Height		3.4mm
Angulation (B)		0˚	30˚
Wall Thickness (C)		0.3mm	N/A
Implant Platform Diameter		3.5mm	5.0mm

Table 3 Design parameters for manufacturing zirconia superstructure and/or hybrid crowns compatible with Tapered Screw-Vent, Trabecular Metal implant systems

DESIGN PARAMETERS FOR MANUFACTURING ZIRCONIA SUPERSTRUCTURES COMPATIBLE WITH TSV IMPLANT SYSTEMS			
Superstructure Parameters		**Superstructure Parameter Values**	
		Min.	**Max.**
Superstructure Gingival Height (A)	0.3mm TiBase Collar Height	0.25mm	5.75mm
	1.3mm TiBase Collar Height		4.3mm
	2.6mm TiBase Collar Height		3.4mm
Angulation (B)		0˚	30˚
Wall Thickness (C)		0.3mm	N/A
Implant Platform Diameter		3.5mm	5.7mm

Table 4 Design parameters for manufacturing zirconia superstructure and/or hybrid crowns compatible with TSX implant system

DESIGN PARAMETERS FOR MANUFACTURING ZIRCONIA SUPERSTRUCTURES COMPATIBLE WITH TSX IMPLANT SYSTEMS			
Superstructure Parameters		**Superstructure Parameter Values**	
		Min.	**Max.**
Superstructure Gingival Height (A)	0.3mm TiBase Collar Height	0.25mm	5.75mm
	1.3mm TiBase Collar Height		4.7mm
	2.6mm TiBase Collar Height		3.4mm
	1.0mm TiBase Collar Height		5.0mm
	1.7mm TiBase Collar Height		4.3mm
Angulation (B)		0˚	30˚
Wall Thickness (C)		0.3mm	N/A
Implant Platform Diameter		2.9mm	4.5mm

Table 5 Design parameters for manufacturing zirconia superstructure and/or hybrid crowns compatible with Eztetic implant systems

DESIGN PARAMETERS FOR MANUFACTURING ZIRCONIA SUPERSTRUCTURES COMPATIBLE WITH EZTETIC IMPLANT SYSTEMS			
Superstructure Parameters		**Superstructure Parameter Values**	
		Min.	**Max.**
Superstructure Gingival Height (A)	1.0 mm TiBase Collar Height	0.25mm	5.0 mm
	1.7 mm TiBase Collar Height		4.3 mm
	2.6 mm TiBase Collar Height		3.4 mm
Angulation (B)		0˚	30˚
Wall Thickness (C)		0.3mm	N/A
Implant Platform Diameter		2.9mm	N/A

The post height of an abutment is the cementable post measured above the gingival margin of the final abutment design including that of the ceramic top-half. The minimum allowable post height for patient-matched Zfx abutments intended for single-unit loading is 4.0 mm.

Pre-milled Abutment Blanks

The Pre-milled Abutment Blank is a cylindrical titanium alloy abutment designed for patient-specific abutment fabrication with CAD/CAM technology. The patient-specific abutment milled from a Pre-milled Abutment Blank is secured directly to the implant using a retaining screw. Pre-milled Abutment Blanks are available in an engaging/hexed design only for single-unit and multi-unit restorations.

Design parameters for the CAD/CAM patient-specific abutment using a Pre-milled Abutment Blank are included in the following table:

Table 6 – Design parameters for manufacturing Pre-milled Blank custom abutments

Description	Min.	Max.
Gingival Margin Height (Collar)	0.25 mm	6.0 mm
Platform Diameter	2.9mm	6.0mm
Angulation	0°	30°
Wall Thickness	0.5mm	N/A
Post Height	4.0 mm	N/A

Retaining Screws

Corresponding retaining screws are packaged with the abutment and replacement screws are available individually. All screws are compatible with the corresponding ZimVie dental implants.

Material Composition

All subject device abutments are made of titanium alloy Ti-6Al-4V ELI conforming to ASTM F136.

Screws are made of either titanium alloy Ti-6Al-4V ELI conforming to ASTM F136, or Gold-Tite® screws with stainless steel conforming to ASTM F138. Gold-Tite screws have a gold-plating conforming to ASTM B488 and ASTM B571.

Zirconia superstructures for use with the TiBase Abutments are made of zirconia conforming to ISO 13356.

Performance Data

Non-clinical testing data submitted to demonstrate substantial equivalence includes: sterilization validation according to ISO 17665-1; biocompatibility testing according to ISO 10993-1 Table A-1, ISO 10993-5, and ISO 10993-10; reverse engineering analysis to confirm compatibility with the Sirona inCoris Meso Blocks; reprocessing validation according to ISO 17665-2, and mechanical testing according to ISO 14801 to determine that the subject device has sufficient strength for its intended use. MR Safety testing was conducted according to ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119 for a determination of MR Conditional.

No clinical data were included in this submission.

Equivalence to Marketed Devices

Zfx Abutments (subject device) are substantially equivalent in design, function, material, and Indications for Use to the Primary Predicate, DESS Dental Smart Solutions abutments cleared in K222288. All are intended for use with endosseous dental implants in the maxilla and mandible to provide support for single and multi-unit restorations.

All digitally designed subject device abutments and primary predicate abutments are to be sent to a validated milling center for manufacture. Subject device abutments are similar in range of sizes, connections, and technological characteristics to the DESS Dental Smart Solutions, K222288. Implant/abutment compatibility for the subject device is substantially equivalent to the primary predicate.

Material for the superstructure of both the subject device and the predicate device is zirconia conforming to ISO 13356. The cement recommended for bonding of superstructures for both the subject device and the predicate device is Multilink Hybrid Abutment Cement.

Table 7 - Substantial Equivalence – Indications for Use

<table>
<tr><th>Subject Device</th><th>Indications for Use Statement</th></tr>
<tr><td>Zfx Abutments</td><td>The Zfx Abutments 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 or superstructures and/or hybrid abutment crowns for use with Zfx TiBase or Pre-Milled Blank Abutments are intended to be sent to a Zfx validated milling center for manufacture.

Table 1 Compatible Implant Systems
<table>
<tr><th>Compatible Implant System</th><th>Platform Ø (mm)</th></tr>
<tr><td rowspan="4">Certain (Tapered and Parallel Walled),
T3, T3 Pro</td><td>3.4</td></tr>
<tr><td>4.1</td></tr>
<tr><td>5.0</td></tr>
<tr><td>6.0</td></tr>
<tr><td rowspan="3">Tapered Screw-Vent,
Trabecular Metal</td><td>3.5</td></tr>
<tr><td>4.5</td></tr>
<tr><td>5.7</td></tr>
<tr><td rowspan="3">TSX</td><td>2.9</td></tr>
<tr><td>3.5</td></tr>
<tr><td>4.5</td></tr>
<tr><td>Eztetic</td><td>2.9</td></tr>
</table>
The Zfx TiBase abutments for the Ø3.25 mm Certain implant bodies, and Ø3.1 mm Eztetic implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.</td></tr>
<tr><td>Primary Predicate Device</td><td></td></tr>
<tr><td>K222288
DESS Dental Smart Solutions</td><td>DESS Dental Smart Solutions abutments 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 Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform Name</th></tr>
<tr><td>Ankylos C/X</td><td>3.5, 4.5, 5.5</td><td>2.52</td></tr>
</table></td></tr>
</table>

	Astra Tech EV	3.0	3.0
		3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Astra Tech OsseoSpeed™	3.0	3.0
		3.5/4.0	3.5/4.0
		4.5/5.0	4.5/5.0
	BioHorizons	3.0, 3.4, 3.8	3.0
		3.8, 4.6	3.5
		4.6, 5.8	4.5
		5.8	5.7
	Biomet 3i Certain®	3.25	3.4
		4.0	4.1
		5.0	5.0
	Biomet 3i OSSEOTITE®	3.25	3.4
		3.75, 4.0	4.1
		5.0	5.0
	Camlog	3.8	3.8
		4.3	4.3
		5.0	5.0
	Dentium SuperLine	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3
	FRIADENT XiVE®	3.4	3.4
		3.8	3.8
		4.5	4.5
		5.5	5.5
	MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
	Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
	NobelActive®, NobelParallel Conical	3.0	3.0
		3.5	NP
		4.3, 5.0	RP
	NobelReplace® Trilobe	3.5	NP
		4.3	RP
Reference Devices			
K100993 Inclusive Titanium Abutments for OsseoSpeed	The Inclusive Titanium Abutments for Astra OsseoSpeed Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astral Tech OsseoSpeed 3.0, 3.5, 4.0,4.5, 5.0 implants.		
K052648 Modification 3i Patient-Specific Dental Abutments	The 3i Patient-Specific Dental Abutments and Overdenture 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 single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.		

and Overdenture Bars	
K092341 Biomet 3i Low Profile Abutments	BIOMET 3i Dental 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 to the abutment.

Table 8 - Substantial Equivalence – Technological Characteristics

Comparison	**Subject Device**	**Subject Device**	**Primary Predicate (K222288)**	**Reference Device (K100993)**	**Reference Device (K052648)**	**Reference Device (K092341)**
	TiBase Abutment **Zfx GmbH**	**Pre-milled Abutment Blank** **Zfx GmbH**	**DESS Dental Smart Solutions** **Terrats Medical SL**	**Inclusive Titanium Abutments for Astra OsseoSpeed** **Prismatik Dentalcraft**	**Modified 3i Patient-Specific Dental Abutments and Overdenture Bars**	**Biomet 3i Low Profile Abutments**
Design						
Platform Diameter (mm)	2.9mm, 3.4mm, 3.5mm, 4.1mm, 4.5mm, 5.0mm, 5.7mm	2.9mm, 3.4mm, 3.5mm, 4.1mm, 4.5mm, 5.0mm, 5.7mm, 6.0mm	4.5 - 6.5mm	3.0-5.0mm	3.4 - 6 mm	3.4-5.0mm
Gingival Height (mm)	0.25-5.75mm	0.25 – 6.0 mm	0.3 – 6.0 mm	Multiple stock abutments	0.25 mm (min)	1.0-5.0mm
Post Height (mm)	4.0. 4.5, 4.75, 5.7	Min = 4.0 mm	4.0, 4.2, 4.5, 4.7mm	Multiple stock abutments	4.5 mm (min)	6.2mm (max)
Abutment Angle	Straight (0 degrees), Up to 30 degrees	Straight (0 degrees), Up to 30 degrees	Straight (0 degrees), Up to 30 degrees	Straight (0 degrees), Up to 30 degrees	Straight (0 degrees), Up to 30 degrees	Straight (0 degrees), Up to 30 degrees
Implant /Abutment Connection	Internal; Engaging; Non-engaging	Internal ; Engaging; Non-engaging	Internal, External Engaging; Non-engaging	Internal	External Hex, Internal	External Hex, Internal
Restoration Type	Single unit & Multi-unit	Single unit & Multi-unit	Single unit & Multi-unit	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	Cement retained	Screw or Cement retained	Screw or Cement retained
Material						
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI Co-Cr-Mo Alloy	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Retaining Screw	Ti-6Al-4V ELI Stainless steel 316L with gold-plating	Ti-6Al-4V ELI Stainless steel 316L with gold-plating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI	Titanium Alloy Gold Alloy	Stainless steel 316L with gold-plating

Conclusion

The subject device has demonstrated substantial equivalence to the predicate device in that it has the same intended use, uses the same operating principle, incorporates the same basic design and materials, and uses the same sterilization method.