July 14, 2023

Zentek Medical LLC
% Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K221673
Trade/Device Name: Bonafix TiBase
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 15, 2023
Received: June 15, 2023

Dear Juan Tezak:

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,

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)*
K221673

Device Name
Bonafix TiBase abutment

Indications for Use *(Describe)*
Bonafix TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Compatible Implant System	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
HIOSSEN ET III	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Nobel Active	3.5	NP
	4.3, 5.0	RP
Straumann Bone Level	3.3	NC
	4.1, 4.8	RC
Zimmer Screw-Vent/ Tapered Screw Vent	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Bonafix 2 Plus Implants	3.5, 3.75, 4.20, 5.0, 6.0	3.5

All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.

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.

510(k) Summary

Bonafix TiBase (K221673)

July 14th, 2023

ADMINISTRATIVE INFORMATION

Applicant

ZENTEK MEDICAL LLC
200 Craig Rd Ste 107
Manalapan, NJ 077268735
Phone: +1 732-2840545

Establishment Registration Number

Official Contact

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Owner
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+1 732-2840545
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Representative/Consultant

Juan Tezak
Carlos Marín
Compliance4Devices
118 W Prive Cr. Delray Beach Fl, 33445
Phone: +1 561-789-2411
E-mail: compliance4devices@gmail.com

DEVICE AND CLASSIFICATION NAME

Device Trade Name:	**Bonafix TiBase**
Common Name:	Dental implant abutment
Classification Regulation:	21 CFR 872.3630
Classification Name:	Endosseous dental implant abutment
Device Classification:	Class II
Classification Panel:	Dental Products Panel
Primary Product Code:	NHA

PREDICATE DEVICE INFORMATION

Primary predicate

K212108, Dynamic Ti-base. Talladium España, SL

Reference Devices

K140934 HIOSSEN ETIII SA. HIOSEEN® Implant

K153758 STRAUMANN DENTAL IMPLANT SYSTEM. STRAUMANN USA

K061410 Tapered Screw-Vent. Zimmer Dental

K142260 Nobel Active conical. Nobel Biocare AB

K153332 ETIII SA Fixture System (Ø3.2mm). HIOSEEN® Implant

K193352 Abutment CAD. Exocad GmbH

K120243 G-CEM LinkAce™. GC AMERICA INC

K133339 Zimmer Dental Tapered Screw Vent T Implant, HA Coated; Zimmer Dental Tapered Screw-Vent M Implant, HA Coated. Zimmer Dental

Intended Use

Bonafix TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Compatible Implant System	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
HIOSSEN ET III	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Nobel Active	3.5	NP
	4.3, 5.0	RP
Straumann Bone Level	3.3	NC
	4.1, 4.8	RC
Zimmer Screw-Vent/ Tapered Screw-Vent	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Bonafix 2 Plus Implants	3.5, 3.75, 4.20, 5.0, 6.0	3.5

All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.

Device Description

The Bonafix TiBase abutment is composed of two-piece abutment that is a titanium base at the bottom and a zirconia superstructure (CAD/CAM patient specific superstructure) at the top. The dental restoration and mesostructure are fabricated using a CAD/CAM process. The subject device abutment platform diameters range from 3.0 mm to 5.7 mm, and the corresponding compatible implant body diameters also range from 3.3 mm to 7.0 mm. The apical end is prefabricated to match the compatible implant platform and is available with implant connections for crowns (engaging) or bridges (non-engaging). Each abutment is provided with a screw designed to match the compatible implant.

The titanium base abutment and screw are manufacturated from titanium alloy conforming to ASTM F136. The superstructure is to be manufactured from zirconia conforming to ISO 13356. The subject devices are provided non-sterile to the end user. All digitally designed superstructures, and/or hybrid crowns for use with Bonafix TiBase abutments are to be sent to a Zentek validated Milling center for manufacture. The zirconia superstructure in straight only and is not to be designed to provide an angle or divergence correction.

The design parameters for the fabrication of the restoration on Bonafix TiBase abutments, which are already locked in the EXOCAD CAD/CAM software (K193352), are as follows:

- Minimum wall thickness – 0.43 mm
- Minimum abutment post height - 4.0 mm
- Maximum post height 6.5 mm
- Maximum gingival height - 5.0 mm
- Minimum gingival height 0.7 mm
- Angulation - 0°

The recommended cement for bonding the zirconia superstructure to the Bonafix TiBase abutments to create the final two-piece abutment is G-CEM LinkAce™ cleared in K120243.

Equivalence to Marketed Device

The subject device is substantially equivalent in indications and design principles to the primary predicate device. Below is a table comparing the indications for use and technological characteristics of the subject device and the primary predicate device.

The subject device is equivalent to the identified primary predicate, with the differences being the compatible implant systems for which the reference devices are included and supported by reverse engineering.

The Indications for Use Statement (IFUS) for the subject device is identical to the identified primary predicate K212108, with the differences being the compatible implant systems for which the reference devices K140934, K153758, K061410, K142260, K153332, and K133339 are included and which are supported by reverse engineering.

The other reference devices K120243 and K193352 serve as references for the cement and software used in the design of the Bonafix TiBase abutment restoration.

Table 1. Comparison with predicate device for Summary

<table>
<tr><th>COMPARISON</th><th>SUBJECT DEVICE</th><th>PREDICATE DEVICE</th><th>COMPARISON</th></tr>
<tr><td>Device</td><td>Bonafix TiBase abutment (K221673)
Zentek Medical LLC</td><td>Dynamic Ti-base (K212108).
Talladium España, SL</td><td></td></tr>
<tr><td>Intended Use</td><td>Bonafix TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>HIOSSEN ET III</td><td>3.5</td><td>Mini</td></tr>
<tr><td></td><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular</td></tr>
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<tr><td></td><td>4.7</td><td>4.5</td></tr>
<tr><td></td><td>6.0</td><td>5.7</td></tr>
<tr><td>Bonafix 2 Plus Implants</td><td>3.5, 3.75, 4.20, 5.0, 6.0</td><td>3.5</td></tr>
</table></td><td>Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.
<table>
<tr><th>Implant Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="4">SPI® CONTACT Dental Implant</td><td>2.7</td><td>3.5</td></tr>
<tr><td>3.5</td><td>4.0</td></tr>
<tr><td>3.5</td><td>4.5</td></tr>
<tr><td>4.2</td><td>5.0</td></tr>
</table></td><td>Similar</td></tr>
</table>

COMPARISON	SUBJECT DEVICE	PREDICATE DEVICE	COMPARISON
	All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.	All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Thommen Medical validated milling center for manufacture.	
Abutment Designs	Titanium Base Engaging	Titanium Base Engaging	Same
	Titanium Base Non-Engaging	Titanium Base Non-Engaging	Same
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Same
Abutment/Implant Platform Diameter (mm)	3.0 – 5.7	3.5, 4.0, 4.5, 5.0	Similar
Abutment Angle	Straight (0°)	Up to 30°	Different
CAD/CAM Abutment Design Parameters			
Minimum post height, mm	4.0	4.0	Same
Maximun post heigth, mm	6.5	9.0	Different
Maximum gingival height, mm	5.0	5.83	Similar
Minimum gingival height, mm	0.7	0.7	Same
Wall Minimum wall thickness	0.43	0.43	Same

COMPARISON	SUBJECT DEVICE	PREDICATE DEVICE	COMPARISON
Maximum abutment angulation	0°	Up to 30°	Different
Abutment attachment to implant	Screw	Screw	Same
Prosthesis attachment to abutment	Cement-retained Screw-retained	Cement-retained Screw-retained	Same
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Same
Abutment/ Implant Interface	Internal connection	Internal	Same
Materials			
Abutment	Ti-6Al-4V alloy (ASTM F136)	Titanium alloy, ASTM F136	Same
Screw	Ti-6Al-4V alloy (ASTM F136)	Titanium alloy, ASTM F136	Same
Superstructure	Zirconia – ISO 13356	Zirconia – ISO 13356	Same

Non-Clinical Testing Summary

Bonafix TiBase underwent evaluation tests based on the following standards:

Table 2 Standards compliance for Summary

ISO 10993-5	2014	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
ANSI/AAMI/ISO 17665-1	(2006/(R)2013)	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, Annex D

End User Sterilization Validation Test according to ISO 17665-1.

Engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility. A plan for ongoing monitoring to ensure continued compatibility is also implemented.

Additional, Non-clinical worst-case MRI review was performed to evaluate the metallic Bonafix TiBase device 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. 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.

Clinical Testing Summary

Clinical testing was not required to demonstrate the substantial equivalence of the Bonafix TiBase to its predicate device.

Conclusion

Based on the information presented in this 510(k), the Bonafix TiBase is considered substantially equivalent to the identified predicate devices.