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

December 20, 2022

Re: K213677
Trade/Device Name: Bonafix 2 Plus
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 22, 2022
Received: November 22, 2022

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)*
K213677

Device Name
Bonafix 2 Plus

Indications for Use *(Describe)*
Bonafix 2 Plus Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Bonafix 2 Plus implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading.

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.

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510(k) Summary

Bonafix 2 Plus

December 12th, 2022

ADMINISTRATIVE INFORMATION

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Establishment Registration Number

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DEVICE AND CLASSIFICATION NAME

Device Trade Name:	**Bonafix 2 Plus**
Common Name:	Endosseous dental implant
Classification Regulation:	21 CFR 872.3640
Classification Name:	Implant, Endosseous, Root-form
Device Classification:	Class II
Classification Panel:	Dental
Primary Product Code:	DZE
Secondary Product Code:	NHA

PREDICATE DEVICES INFORMATION

Primary predicate

K191443, MSDI Dental Implants System

Reference devices

K191191 Neodent Implant System - Temporary Abutments
K160213, s-Clean Tapered II RBM Implant System

Intended Use

Bonafix 2 Plus Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Bonafix 2 Plus implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading.

Device Description

The current submission requests clearance for the Class II Bonafix 2 Plus implant system. The Bonafix 2 Plus Implant is a bone level type implant, built in Grade 5 ELI Titanium Alloy and treated with RBM technology. The implant has a conventional internal hex connection style. The crestal zone of implant have micro-rings. The design crestal zone (straight or tapered) depends on Implant diameter because the implant system has only one platform. The body of the implant is tapered, designed with a double progressive thread with a small internal channel at the bottom of the thread; and the apex of the implant has a flat shape. Has two-spiral channel at the apical end of the implant that provide self-tapping properties to the implant.

The implants are provided in several different dimensions, 3.5, 3.75, 4.2, 5.0, and 6.0mm of diameter, and lengths of 8, 10, 11.5, 13 and 16mm. Hex Connection 6.0 diameter implants do not come in 13 or 16mm length.

Cover screw, Healing Caps (3.8 and 4.6mm of diameters) and 3 types of abutments: Straight abutments, Angled abutment and Multi-unit abutments, are included in the system.

Equivalence to Marketed Device

Bonafix 2 Plus is substantially equivalent to the MSDI Dental Implants System (K191443) predicate device in almost all of its characteristics. Is similar in terms of intended use, indications for use, operating principle, fundamental scientific technology, implant connections and material. The technological characteristics such as implant diameters, length, connection and platform geometry, as well as mating abutments are similar to that of the predicate devices, except for the temporary abutments which are similar to the reference device K191121.

Other differences with predicate device are on the surface treatment (RBM vs Grit blasted + Acid Etched Surface) but here is similar to reference device K160213.

The basis for Zentek Medical LLC belief that Bonafix 2 Plus is substantially equivalent to the predicated and referenced device is summarized in the following Tables of Substantial Equivalence.

Table 1. Comparison with predicate device

Feature	Subject Device	Primary Predicate Device	Comparison
Device Trade Name	**Bonafix 2 Plus**	**MSDI Dental Implants System**	
Indications for Use	Bonafix 2 Plus Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Bonafix 2 Plus implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading.	MSDI Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Same
Connection	Internal hex	Internal Hexagon	Same
Diameter of Implants Hex Connection	3.5mm 3.75mm 4.2mm 5.0mm 6.0mm	3.3, 3.7, 4.2, 5.0 and 6.0 mm	Similar. The predicate device has a smaller diameter implant. This does not affect the substantial equivalence of the device. a worse performance scenario
Implant Lengths (mm)	Ø 3.5mm (8,10,11.5,13,16) Ø 3.75mm (8,10,11.5,13,16) Ø 4.2mm (8,10,11.5,13,16) Ø 5.0mm (8,10,11.5,13,16) Ø 6.0mm (8,10,11.5)	8, 10, 11.5, 13 and 16mm	Same
Material	Ti-6Al-4V ELI (ASTM F136)	Titanium Alloy – Ti6Al4V ELI	Same
Cover screw	One size	One size	Same
Surface Treatment	RBM	Grit Blasted and Acid Etched Surface	Different Same as Reference device K160213
Sterilization of Implants	Gamma ray	Gamma ray	Same

Feature	Subject Device	Primary Predicate Device	Comparison
Device Trade Name	Bonafix 2 Plus	MSDI Dental Implants System	

Table 2. Comparison with predicate and referenced device for abutments

Feature	Subject Device	Primary Predicate Device	Reference Device	Comparison
Device Trade Name	**Bonafix 2 Plus**	**MSDI Dental Implants System (1)**	**Neodent Implant System - Temporary Abutments (2)**	
Straight abutments	• Straight abutment Ø4.5 / Length: 9 and 13 mm Ø5.5 mm / Length: 9 and 12 mm • Straight abutment w/shoulder Ø Standard / Tissue height: 1, 2 and 3 • Anatomic straight abutment Ø Standard / Tissue height: 1, 2 and 3.	• Standard Titanium Abutment with height of 7mm • Standard narrow abutment with heights of 7, 9, and 11mm	N/A	(1) Similar. The subject device has additionally anatomical and w/shoulder abutments. (2) N/A
Angled abutments	• Angled abutments Ø Standard Degrees: 15° and 25° • Anatomic angled abutment Ø Standard Degrees: 15° Tissue height: 1, 2 and 3. • Anatomic angled abutment Ø Standard Degrees: 25° Tissue height: 1 and 2.	• Standard 15° Abutment with heights of 8, 12, and 13mm. • Standard 25° Abutment with heights of 9 and 12mm	N/A	(1) Similar. The subject device has additionally anatomical angled abutments. (2) N/A
Multi-unit abutment (*)	• Multi-unit straight abutment Ø Standard Tissue height: 1, 2, 3 and 4 • Angled multi-unit abutment Ø Standard Degrees: 17° Tissue height: 2 and 3 Degrees: 30° Tissue height: 3 and 4	Multi-unit abutments in heights of 1,2,3 and 4 mm.	N/A	(1) Similar. The subject device has additionally angled multi-unit abutments. (2) N/A

Feature	Subject Device	Primary Predicate Device	Reference Device	Comparison
Device Trade Name	**Bonafix 2 Plus**	**MSDI Dental Implants System (1)**	**Neodent Implant System - Temporary Abutments (2)**	
Temporary abutments	**Design:** Straight, cylindrical with retention rings. **Model:** With Hex and Without Hex **Diameter (Ø):** 3.5 **Angulation:** Straight **Duration of use:** 180 days	N/A	**Design:** Straight, cylindrical with retention rings. **Model:** With Hex and Without Hex **Diameter (Ø):** 3.5 and 4.5 **Angulation:** Straight **Duration of use:** 180 days	(1) Different (2) Same as the reference device.
Sterilization of abutments	Steam sterilization	Steam sterilization	Ethylene Oxide to an SAL of 1x10-6	(1) Same as the reference device. (2) Different
Material	Ti-6Al-4V ELI (ASTM F136)	Titanium Alloy – Ti6Al4V ELI	Ti-6Al-4V ELI	(1) Same (2) Same

***These models of abutments are not for single crown use.**

Non-Clinical Testing Summary

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device based on the following standards:

Table 3 Standards compliance

Standard	Version	Title
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.
ISO 10993-12	2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.
ASTM F2096-11	2013	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test).
ISO 10993-5	2014	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
ISO 14801	2016	Dentistry--Implants--Dynamic Fatigue Tests for Endosseous Dental Implants.
ASTM F1980-16	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
ASTM F88	2016	Standard Test Method for Seal Strength of Flexible Barrier Materials (Peel Test).
ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
ISO 11607-1	2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO 11137-1	2006/(R)2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
ISO 11137-2	2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

A testing has been conducted to substantiate sufficient fatigue endurance limits for the Bonafix 2 Plus Implants for placement in the anterior and posterior regions of the mouth with compatible abutments. Testing has been performed in accordance with ISO 14801:2016 and FDA Class II Special Controls Guidance Document for Root-form Endosseous Dental Implants. The worst-case scenario for the subject devices has demonstrated substantially equivalent to others device legally marketed regard to mechanical performance.

Non-clinical worst-case MRI review was performed to evaluate the metallic Bonafix 2 Plus Implant System 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. 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.

Radiation sterilization validation according to ISO 11137-1 and 11137-2 was provided, demonstrating a sterility assurance level (SAL) of 10-6 and accelerated aging study demonstrating a shelf life of one (5) year.

Steam sterilization validation according to ISO 17665-1 was provided, demonstrating a sterility assurance of sterilization protocol of abutment.

SEM/EDS analysis for worst-case representative implant body was conducted on the subject devices to assess the presence of residual blast media particles on the device due to the modification of the surface treatment in the subject device. SEM/EDS analysis has demonstrated that after the surface treatment the implant doesn't have any different components than Titanium alloy ASTM F 136.

Biocompatibility assessment of the final finished device per recommendations of current FDA guidance (issued on September 4, 2020) in accordance to "ISO 10993-1, Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process" has been conducted. It is concluded that the Bonafix 2 plus Implants are substantially equivalent to the predicate devices in terms of biocompatibility inclusive of base materials, manufacturing processes inclusive of surface treatments.

Pyrogenicity information provided is based on FDA Guidance on “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile, issued on 21 January 2016.” The method to be used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device. This test will be conducted on every batch. The subject devices will not be labeled as non-pyrogenic or pyrogen-free, nor will any claims be made in regards to non-pyrogenicity.

Clinical Testing Summary

Clinical testing was not required to demonstrate the substantial equivalence of the Bonafix 2 Plus to its predicate device.

Conclusion

Based on the information presented in these 510(k) premarket notifications the Bonafix 2 Plus is considered substantially equivalent (as safe, as effective and performs as well as) to the currently marketed and referenced devices: K191443, MSDI Dental Implants System and Neodent Implant System (K191191), citied in this submission. The differences noted between the Bonafix 2 Plus and the predicate device do not impact safety or effectiveness based on the successfully conducted testing of the subject device.