



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

BONAFIX Surgical and Dental Implants, LLC
Juan Tezak
President
118 W Prive Circle
Delray Beach, Florida 33445

July 14, 2017

Re: K162853
Trade/Device Name: Bonafix TWO - Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 14, 2017
Received: June 14, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mary S. Runner -A

Lori A. Wiggins, MPT, CLT
Acting Director

Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

SECTION 2

Indications for Use

510(k) Number (if known): K162853

Device Name: Bonafix TWO – Dental Implant System

Indications for Use:

The **Bonafix TWO** Dental Implant System is indicated for delayed loading in surgical and restorative applications placement in the upper or lower jaw and to provide support for prosthetic devices such as artificial teeth with the goal of restoring the patient's chewing function.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**SECTION 3
510(k) Summary**

K162853

SUBMITTER/510(K) HOLDER:

Sponsor: BONAFIX Surgical and Dental Implants, LLC
 Address: 118 W Prive Cr.
 Delray Beach Fl, 33445
 Contact: Juan Tezak
 Juan@Bonafixsdi.com
 (561) 789-2411
 Date Prepared: September 20, 2016

DEVICE IDENTIFICATION:

Device Trade Name: **Bonafix TWO - Dental Implant System**
 Common Name: Endosseous dental implant
 Classification Regulation: 21 CFR 872.3640
 Classification Name: Implant, Endosseous, Root-form
 Device Classification: Class II
 Classification Panel: Dental
 Product Code: DZE

PREDICATE DEVICE:

Predicate Device	510 (k) No.	Predicate Type
MIS Dental Implant System MIS – Implant Technologies Ltd. (Israel)	K040807	Primary Predicate
Minifix Implant Bonafix Surgical and Dental Implants, LLC (USA)	K122052	Reference Predicate

DEVICE DESCRIPTION:

Bonafix TWO Implant is a bone level type implant indicated for delayed loading only, built in Grade 5 ELI Titanium Alloy and treated with RBM technology. To prevent unnecessary rotations between the implant and the abutment, the implant has an internal hex connection style. The body of the implant is tapered, the implant neck is straight and has micro-rings; and the apex of the implant has a dome shape. Was designed with a double-thread that has a constant depth and thickness. Has two-spiral channel at the apical end of the implant that provide self-tapping properties to the implant. This system has 3.35, 3.75, 4.20, 5.00, 6.00 diameter distributed in three (3) platform (Narrow, Standard and Wide) and 8, 10, 11.5, 13 and 15 mm lengths. The 3.35 mm diameter excludes the 8 mm length, and the 6.00 mm diameter excludes the 15 mm length. The implants are provided sterile and are ready to be implanted. The system includes various prosthetic device such as, Cover screw, Healing caps, and two (2) abutments, Straight abutments and Angle abutments. All abutments are connected to implant through the hex and secured by retained screw. The Straight abutment has 2 to 3 emergence

profiles depending on platform. The Angle abutments has a single emergence profile by platform. The angle abutment has axis inclined of 20° compared to the implant’s axis. The abutments are provided non-sterile and are intended to be sterilized before use. All prosthetic device are made in Grade 5 ELI Titanium Alloy.

INDICATION FOR USE STATEMENT:

The Bonafix TWO Dental Implant System is indicated for delayed loading in surgical and restorative applications placement in the upper or lower jaw and to provide support for prosthetic devices such as artificial teeth with the goal of restoring the patient's chewing function.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

Based on its design, indications for use, materials, manufacture methods and sterility, the proposed Bonafix TWO implant is deemed to be substantially equivalent to the following two-stage implant device: The MIS Dental Implant System (Specifically the SEVEN line of implants) from MIS Implant Technologies.

The table that follows provides additional details on the equivalence of Bonafix TWO with the predicate devices.

	Bonafix TWO – Dental Implant System	MIS Dental Implant System (SEVEN line of Implants)
510k Number	This Submission	K040807
Product Code	DZE	DZE
Endosseous Dental Implants	Root-form tapered	Root-form tapered
Indications for use	Implant System is indicated for delayed loading in surgical and restorative applications placement in the upper or lower jaw and to provide support for prosthetic devices such as artificial teeth with the goal of restoring the patient's chewing function.	Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient's chewing function.
Design implant	<u>Implant Type:</u> Bone-level implant <u>Connection Type:</u> Internal hex connection. For Standard and Wide platform the internal hex is 2.45mm and Narrow platform the internal hex is 2.10mm <u>Neck Design:</u>	<u>Implant Type:</u> Bone-level implant <u>Connection Type:</u> Internal hex connection. For Standard and Wide platform the internal hex is 2.45mm and Narrow platform the internal hex is 2.10mm <u>Neck Design:</u>

	<p>Straight walled neck with micro-rings. <u>Body Design:</u> Tapered design with a double-thread that has a constant depth and thickness. <u>Apex Design:</u> Dome shape with two-spiral channel.</p>	<p>Lightly tapered walled neck with micro-rings. <u>Body Design:</u> Tapered design with a double-thread that has a constant depth and thickness. <u>Apex Design:</u> Dome shape with three-spiral channel.</p>
Diameter Implants	3.35mm, 3.75mm, 4.20mm, 5.00mm, 6.00mm	3.30mm, 3.75mm, 4.20mm, 5.00mm, 6.00mm
Length Implants	8mm, 10mm, 11.5mm, 13mm, 15mm	6mm, 8mm, 10mm, 11.5mm, 13mm, 16mm
Material	Titanium Grade 5 6Al-4V ASTM F136	Titanium Grade 4 Pure Titanium ASTM F67
Fixture Sterile	Yes	Yes
Sterilization method	Gamma Ray	Gamma Ray
Surface Finish	Technology RBM	Sandblasted with Acid Etched
Cover Screw	<p>The implants are supplied together with cover screws, manufactured from titanium Ti-6AL-4V. The cover screws is placed in the implant during the integration period between the implant and the bone. They completely occlude the internal surface, keeping it free from ingrowth of bone and debris. The cover screw is supplied sterile together with the implant in the same individual package.</p>	<p>The implants are supplied together with cover screws, manufactured from titanium grade 4. The cover screws is placed in the implant during the integration period between the implant and the bone. This completely occlude the internal surface, keeping it free from ingrowth of bone and debris. The part is supplied sterile together with the implant in the same individual package.</p>
Abutment system	<p>Contained abutments in the System are straight and angled dental implant abutments intended to be connected to the fixture with crew, for screw retained and cemented restored. The abutments fit in/on the hexagonal part of the implant and deliver maximum stability with the use of the screw. The abutments contain Healing Caps, Straight abutment, Angle abutment.</p>	<p>Anatomic abutments are used in conjunction with the implants for screw retained or cemented reconstruction. The abutments fit in/on the hexagonal part of the implant and deliver maximum stability with the use of the screw. The abutment contains temporary abutments, Plastic and Gold-plastic cylinder abutments, Ball attachment system and bar and screw attachment system.</p>
Materials Abutment	<p>For Abutments and Healing Caps is used the titanium Ti-6Al-4V.</p>	<p>Abutments are manufactured in ceramic and titanium. Plastic and Gold-Plastic abutments are manufactured in burn-out plastic and gold.</p>

Angulation for angle abutments	20°	20°
Fixture Sterile (Abutments)	NO, the user can sterilize these parts of the system. Labeling contains instructions for sterilization.	NO

In addition to the two-stage implants listed as predicate devices, this submission references also the Minifix one stage mini-implant as equivalent in terms of composition, biocompatibility and sterility. Details shown in the tables that follow:

	Bonafix TWO – Dental Implant System	MINIFIX
510k Number	This Submission	K122052
Material	ASTM F136 (Ti-6Al-4V Extra Low Interstitial)	ASTM F136 (Ti-6Al-4V Extra Low Interstitial)
Fabrication	MACHINING PROCESS (Turning, Milling, Drilling, Tapping in Lathe Swiss Type)	MACHINING PROCESS (Turning, Milling, Drilling, Tapping in Lathe Swiss Type)
Surface Treatment	RBM	RBM
Supplier	JACKSONVILLE ADVANCE MACHINE (Actually)	JACKSONVILLE ADVANCE MACHINE (Actually)
Device duration in body	LONG TERM USE	LONG TERM USE

PERFORMANCE DATA

Additionally BONAFIX has conducted laboratory testing and determined device functionality and conformance to design input requirements. Non-clinical Testing of the subject device included the following:

- Biocompatibility tests according to ISO 10993-5:2009.
- Bacterial Endotoxins Test, Limulus Amebocyte Lysate (LAL) according to USP <85>
- Fatigue Testing according to ISO 14801:2007
- Sterilization validation test according to ISO 11137-1, ISO 11137-2, ISO 11137-3, ISO 17665-1, and ISO 17665-2

As a result,

- Regarding the fatigue testing of BONAFIX TWO implants and the predicate devices were comparable.
- Regarding the cytotoxicity testing has demonstrated the biocompatibility of the devices.
- Regarding the sterility validation testing was performed and is demonstrated the equivalence of the devices to their predicates.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device and the predicate device have slight differences in the language of the Indications for Use Statements; however, these slight differences do not change the intended use of the device. The subject device and the predicated device also have similar technological characteristics, and are made of similar, if not identical materials; the material is supported by reference device. The subject device and predicate device encompass a very similar or the exact same range of physical dimensions, including diameter and length of the implants and diameter, height and angle of the abutments and a comparative surface area.

CONCLUSION

Based on the foregoing, and in accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, BONAFIX SDI has demonstrated that the BONAFIX TWO Implant System is substantially equivalent to the predicate device legally marketed in terms of intended use, material composition, fundamental scientific technology, principles of operation, and basic design.