K122052

SECTION 3

NOV 2 8 2012

510(k) Summary

Device Name: **MiniFix Implant**

Date Prepared: July 2, 2012

Sponsor: BONAFIX Surgical and Dental Implants, LLC
118 W Prive Cr.
Delray Beach Fl, 33445

Contact: Juan Tezak
Juan@Bonafixsdi.com
(561) 789-2411

Device and Classification Name

- **Device Trade Name: MiniFix Implant**
- **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**: NZE

Predicate Devices:

- MDI MII One-Piece Implant 2.9mm; Imtec Corp.(USA) – (reference 510(k) K081653, determined substantially equivalent on September 19th, 2008)

- Inclusive Mini Implant; Prismatik Dentalcraft, Inc. (USA) – (reference 510(k) K100932, determined substantially equivalent December 27, 2010.

- Mini Drive-Lock Dental Implant System; Intra-Lock International (USA) – (reference 510(k) K070601, determined substantially equivalent October 12, 2007)

Device Description:

Built in Grade 5 ELI Titanium Alloy and treated with RBM technology, the proposed MiniFix implants are designed for both provisional and permanent implementations of single-unit or multi-unit restorations.

The major component of the MiniFix Implant consists of a one-piece, root-form, self-tapping screw. This implant is offered in two models, each with its own applicability: MiniFix Ball and MiniFix One..

The MiniFix Ball implant provides a spherical head that allows for easy placement and removal of both partial and full dentures. Additionally, this model is available in an option without the RBM treatment for use in transitional applications (temporary dentures).

Minifx One is a single piece implant that provides a flat head for permanent installation of single crowns.

The table below shows the available models and sizes for Minifix Ball and Minifix One implants:

Catalog numbers of the Proposed MiniFix Implants			
MiniFix Ball			
Diameter	**Length (11 mm)**	**Length (13 mm)**	**Length (15 mm)**
2.0	MFB2011L	MFB2013L	MFB2015L
2.4	MFB2411L	MFB2413L	MFB2415L
2.9	MFB2911L	MFB2913L	MFB2915L
MiniFix One			
2.9	MFO2911S	MFO2913S	MFO2915S
Transitional MiniFix Ball (No surface treatment)			
2.0	MFBT2011L	MFBT2013L	MFBT2015L
2.4	MFBT2411L	MFBT2413L	MFBT2415L
2.9	MFBT2911L	MFBT2913L	MFBT2915L

As shown on the table, Minifix Ball is available in the same 9 sizes for both Transitional and Permanent implants while the square Minifix One is available for 11, 13 and 15 mm lengths but with a single diameter at 2.9mm.

Intended Use: The proposed MiniFix Implant system consists of MiniFix One and MiniFix Ball implants.

The MiniFix One implants are indicated to provide support for single unit dental prostheses in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The MiniFix One implant must be splinted if two or more are used adjacent to each other. The MiniFix One implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

The MiniFix Ball implants are intended to be placed throughout the maxillary and mandibular arches to provide support for multi-unit restorations on long-term or short term fixation of upper and lower dentures. Immediate loading should only be done in the presence of primary stability and appropriate occlusal loading.

Non-Clinical Test Data: Minifx Implants do not introduce new issues for materials, design, surface treatment, fatigue testing and risk management that have not been addressed in all other substantially equivalent predicate devices.

Substantial Equivalence to Predicate Devices: The proposed **MiniFix Implant** is substantially equivalent to the MDI MII One-Piece Implant 2.9mm from Imtec Corp., the Inclusive Mini Implant from Prismatik and the Mini Drive-Lock Dental Implant System from Intra-Lock International. All these are single-piece implants manufactured with the same titanium alloy and combine a screw section for implant insertion with an abutment section that supports either a denture application or a permanent crown.
All three implants are provided sterile and are intended for use in long term applications as well as in temporary scenarios in which provisional dentures are required to provide time for permanent implants to osseointegrate before installation of crowns. The table that follows provides

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additional details on the equivalence of the three devices.

	Bonafix's MiniFix Implant	IMTEC MDI MII One-Piece Implant ,2.9mm	Prismatik's Inclusive Mini Implant	Mini Drive-Lock Dental Implant System
510k Number	This Submission	K081653	K100932	K070601
Composition	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Diameter (mm)	2.0,2.4,2.9	2.9	2.2, 2.5, 3.0	2.0,2.5
Length (mm)	11,13,15	10,13,15,18	10,13,15	10,11.5,13,15,18
Head	O-Ball, Square	O-Ball, Square	O-Ball	O-Ball
Driver Connection	Square	Square	Square	Square
Housing/O-Ring	Titanium Alloy/EPDM	Titanium Alloy/EPDM	Titanium Alloy/EPDM	Titanium Alloy/EPDM
Indications	The proposed MiniFix Implant system consists of MiniFix One and MiniFix Ball implants. The MiniFix One implants are indicated to provide support for single unit dental prostheses in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The MiniFix One implant must be splinted if two or more are used adjacent to each other. The MiniFix One implant may be immediately restored with a temporary prosthesis that is not in functional occlusion. The MiniFix Ball implants are intended to be placed throughout the maxillary and mandibular arches to provide support for multi-unit restorations on long-term or short term fixation of upper and lower dentures. Immediate loading should only be done in the presence of primary stability and appropriate occlusal loading.	The MII Implant is intended to support single unit or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII Implant is indicated for immediate loading when good primary stability is achieved. Additionally this device permit stability and long term fixation of upper and lower dentures in edentulous cases	Inclusive Mini Implants are self-tapping threaded titanium screws indicated for long term applications. Inclusive Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	Mini Drive-Lock TM Dental Implants are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications. Mini Drive-Lock TM Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.
Sterility	Sterile	Sterile	Sterile	Sterile

Correspondence of predicates to the specific Minifix options are shown in the table below:

Diameter(mm)/ Lengths(mm)	Equivalent To:
Minifix Ball	
2.0 / 11, 13,15	**Mini Drive-Lock Dental Implant System 2.0mm**
2.4 / 11, 13, 15	**Prismatik's Inclusive Mini Implant 2.2mm & 2.5mm**
2.9 / 11,13,15	**Prismatik's Inclusive Mini Implant 2.5mm & 3.0mm**
Minifix One	
2.9	**IMTEC MDI MII One-Piece Implant 2.9mm**

Comparison of Technological Differences: There are no known technological differences between the proposed **MiniFix Implant** and the predicate devices specified in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 28, 2012

Mr. Juan Tezak
President
BONAFIX Surgical and Dental Implants, Limited Liability Company
118 West Prive Circle
Delray Beach, Florida 33445

Re: K122052
Trade/Device Name: MiniFix Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 17, 2012
Received: October 17, 2012

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Susan Runner DDS, MA 2012.11.28 13:01:38 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: MiniFix Implant

Indications For Use:

The proposed MiniFix Implant system consists of MiniFix One and MiniFix Ball implants.

The MiniFix One implants are indicated to provide support for single unit dental prostheses in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The MiniFix One implant must be splinted if two or more are used adjacent to each other. The MiniFix One implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Susan Runner DDS, MA 2012.11.28 13:03:11 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number:_____