



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Vilex (in Tennessee), Incorporated
% Abraham Lavi, Ph.D.
Consultant
Vilex, Incorporated
8374 Market Street, #167
Lakewood Ranch, Florida 34202

November 10, 2015

Re: K150211

Trade/Device Name: EzFuze™ Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 25, 2015
Received: September 28, 2015

Dear Dr. Lavi:

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 Parts 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" (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 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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Manufacturer of Vilex™ bone implants,
Power equipment & surgical instruments

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111 Moffitt Street
McMinnville, TN 37110 USA
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INDICATIONS FOR USE

510(k) NUMBER:

DEVICE NAME: EzFuze™ Implant System

INDICATIONS FOR USE:

The EzFuze Implants have the following Indications for Use:

Fixation of osteotomies and reconstruction of the lesser toes and lesser fingers following correction procedures for hammertoe, claw toe, mallet toe, and other deformities of the feet and hands.

Prescription Use X
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (DOE)



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McMinnville, TN 37110 USA
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510(k) Summary EzFuze Implant System

Sponsor:	Vilex in Tennessee, Inc
Contact Person:	Abraham Lavi
Date Prepared:	September 25, 2015
Trade Name:	EzFuze Implant System
Common Name:	Threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener
Product Code:	HWC/ Orthopedics, Class II
Predicate Devices:	Trident Fusion Implant by Vilex (K141937) SmartToe and X-Fuse by Styker (K070598 and K112197) OSSplate Hammerlock by BioMedical Enterprises (K091951 and K131640) DigiFuse by Metasurg (K111536) eZ-Staple Superelastic Bone Fixation Staple by Vilex (K112837) Newdeal K-wire by Newdeal (K022599)
Description of Device:	The Vilex EzFuze Implant System includes single-piece devices intended for the fixation of PIP joints in lesser toes and digits. Two styles are offered: EzFuze Implant with barbed prongs on both ends and Hybrid EzFuze Implant with a screw design at one end and the other end includes barbed prongs. The EzFuze and Hybrid EzFuze Implants are offered straight or with a 10° bend.
Indications for Use:	The EzFuze Implants have the following Indications for Use: Fixation of osteotomies and reconstruction of the lesser toes and lesser fingers following correction procedures for hammertoe, claw toe, mallet toe, and other deformities of the feet and hands.
Technological Characteristics:	The technological characteristics for the EzFuze Implant System are the same as the characteristics of the predicate devices. All of the sizes included in the Vilex EzFuze Implant system are within the range of offerings of the predicate devices and the designs of the EzFuze devices are similar to the predicate devices. The materials used to manufacture the EzFuze Implants are the same as those used to manufacture the predicate devices.
Substantial Equivalence	The design features of the EzFuze Implant System are substantially equivalent to the design features of other predicate devices previously cleared for market. The methods used to establish equivalence are indications for use, material of construction, sizes, and shapes. The safety and effectiveness of the EzFuze Implant System are adequately supported by the substantial equivalence information, material information and analysis data provided within this Premarket Notification. Therefore, it is concluded that the EzFuze Implant System is substantially equivalent to the noted predicate devices.

510(k) Summary
EzFuze Implant System

Conclusions:	While the EzFuze Implant System is not identical to the predicate devices, any differences that may exist do not significantly affect device safety and effectiveness. In addition, the differences do not add new or increased risks and complications. Therefore, it is concluded that the EzFuze Implant System is substantially equivalent to the predicate devices as outlined previously and should not render the subject device NSE.
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