DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 24, 2016

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

Re: K151881
Trade/Device Name: X-Fix Line Additions
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: February 19, 2016
Received: February 22, 2016

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

ADVANCE WITH US

INDICATIONS FOR USE

510(k) NUMBER: K151881

DEVICE NAME: X-Fix Line Additions

INDICATIONS FOR USE:

The Vilex X-Fix is intended for external fixation with the following indications:
1. Stabilization of Fractures & Osteotomy
2. Adult and Pediatric Leg Lengthening
3. Correction of Bone Deformity in Upper & Lower Extremities

The P&C Software is intended to be used as a component of multilateral external fixation system for the indications listed above.

Prescription Use _____X_____
(Per 21 CFR 801.109)

_____
Concurrence of CDRH, Office of Device Evaluation (DOE)

ADVANCE WITH US

510(k) Summary K151881

Sponsor:
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Phone: (931) 474-7550
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Contact: Abraham Lavi

Date Prepared: March 17, 2016

Trade Name: X-Fix Line Additions

Common Name: External Fixation System

Classification: 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Product Code: KTT/OSN/Orthopedics, Class II

Predicate Devices: Smith & Nephew's Taylor Spatial Frame (K110069, K093047, and K970748)
Smith & Nephew's Ilizarov External Fixator (K870961)
Orthofix's TL-HEX Truelok Hexapod System (K141078)
Vilex's X-Fix (K052196)

Description of Device:
The X-Fix Line Additions, subject of this 510(k) submission, include External Fixation Rings and Footplates, External Fixation Struts, External Fixation Assembly Accessories, and P&C Software. The line additions are manufactured from stainless steel and aluminum materials in various sizes to accommodate patient needs. The X-Fix Line Additions are used with the X-Fix system.

Indications for Use:
The Vilex X-Fix is intended for external fixation with the following indications:
1. Stabilization of Fractures & Osteotomy
2. Adult and Pediatric Leg Lengthening
3. Correction of Bone Deformity in Upper & Lower Extremities

The P&C Software is intended to be used as a component of multilateral external fixation system for the indications listed above.

Technological Characteristics:
The technological characteristics for the X-Fix Line Additions are the same as the characteristics of the predicate devices. The line additions are manufactured in similar sizes and designs as the predicate devices. In addition, the line additions are manufactured from the same materials as the predicate devices.

Performance Data:
The X-Fix Line Additions were evaluated according to FDA's "Reviewers Guidance Checklist for Orthopedic External Fixation Devices" dated February 21, 1997. Applicable mechanical testing was conducted per ASTM F1541-02 (Sections A6 and A7). All testing confirmed that the device is capable of withstanding expected *in vivo* loading.

Software verification and validation documentation and testing was completed in conformance with FDA guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" dated January 11, 2002. The results of software V&V testing indicate that the software performed as intended.

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the X-Fix Line Additions.

Clinical data was not needed to support the safety and effectiveness of the X-Fix Line Additions.

Substantial Equivalence
The design features of the X-Fix Line Additions are substantially equivalent to the design features of other predicate devices previously cleared for market. The methods used to establish equivalence are based on the comparison of the intended use, product technical characteristics, performance characteristics, and mechanical testing. The safety and effectiveness of the X-Fix Line Additions are adequately supported by the substantial equivalence information, material information, analysis data, and testing provided within this Premarket Notification. Therefore, it is concluded that the X-Fix Line Additions are substantially equivalent to the noted predicate devices.

Conclusions
While the X-Fix Line Additions are 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 X-Fix Line Additions are substantially equivalent to the predicate devices as outlined previously and should not render the subject device NSE.