DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 13, 2017

Vilex in Tennessee, Inc.
% Dr. Abraham Lavi
Consultant
Vilex, Inc.
8374 Market Street, #167
Lakewood Ranch, Florida 34202

Re: K163487
Trade/Device Name: Ultima HA Coated Half Pins And Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDW
Dated: November 21, 2016
Received: December 12, 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 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,

Mark N. Melkerson -S

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

Enclosure

Vilex in Tennessee, Inc.
111 Moffitt Street • McMinnville, TN 37110
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Email: info@vilex.com • www.vilex.com

"We'll Wait on You Hand and Foot"

INDICATIONS FOR USE

510(k) NUMBER: K163487

DEVICE NAME: Ultima HA Coated Half Pins and Wires

INDICATIONS FOR USE:

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

Prescription Use _____X_____
(Per 21 CFR 801.109)

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

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510(k) Summary
K163487

Sponsor:	Vilex in Tennessee, Inc.
Contact:	Abraham Lavi
Date Prepared:	June 16, 2014
Trade Name:	Ultima HA Coated Half Pins & Wires
Common Name:	Bone fixation fastener
Classification:	21 CFR 888.3040 – Smooth or threaded metallic bone fastener
Product Code:	JDW/Orthopedics, Class II
Predicate Devices:	Ultima HA Coated Half Pins and Wires by Vilex (K132820)

Description of Device:
This submission includes medical grade stainless steel half pins and wires coated with Hydroxyapatite (HA). They are intended to be used with external fixation systems.

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

Technological Characteristics:
The technological characteristics for the Modified Ultima HA Coated Half Pins and Wires are the same as the characteristics of the predicate devices. All of the sizes included in the Vilex Modified Ultima HA Coated Half Pin and Wire system are within the range of offerings of the predicate devices and the designs of the Vilex devices are similar to the predicate devices. The materials used to manufacture the Vilex Ultima devices are the same as those used to manufacture the predicate devices. In addition, pyrogen testing has been conducted and has confirmed that the device is non-pyrogentic.

Substantial Equivalence
The design features of the Modified Ultima HA Coated Half Pins and Wires 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, and sizes. The safety and effectiveness of the Modified Ultima HA Coated Half Pins and Wires are adequately supported by the substantial equivalence information, material information and analysis data provided within this Premarket Notification. Therefore, it is concluded that the Modified Ultima HA Coated Half Pins and Wires are substantially equivalent to the noted predicate devices.

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Conclusions

While the Modified Ultima HA Coated Half Pins and Wires 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 Modified Ultima HA Coated Half Pins and Wires are substantially equivalent to the predicate devices as outlined previously and should not render the subject device NSE.