NOV 2 2 2005

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

Phone: (412) 655-7550
FAX: (412) 655-7551
www.vilex.com

345 Old Curry Hollow Road
Pittsburgh, PA 15236 USA
E-mail: info@vilex.com

510(K) SUMMARY
Vilex External Fixation System, X-Fix

Date of submission	6/7/05
Type of submission	510(k)
Reason for submission	New device
Product Code	KTT, JDW CFR-21 888.3030, CFR-21 888.3040
Device Class	I
Classification Panel	Orthopedics
Predicate Devices: K043174 K955848 K970290	 R&R Medical, Inc. Orthofix EBI
Common/Generic	External Ring Fixation
Device Trade Name	Vilex External Fixation System, X-Fix
Establishment Reg. No.	2529556
Owner Operator No.	9004058
Establishment Operations	Manufacturer
Indication 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.
Submitter	A. Lavi

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2005

Dr. Abraham Lavi, Ph.D., M.B.A.
President
Vilex, Inc.
345 Old Curry Hollow Road
Pittsburgh, Pennsylvania 15236

Re: K052196
Trade/Device Name: X-Fix
Regulation Number: 21 CFR 888.3030
Regulation Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple
Regulatory Class: II
Product Codes: KTT, JDW
Dated: October 05, 2005
Received: October 27, 2005

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE:

510(K) NUMBER: **K052196**

DEVICE NAME: **VILEX EXTERNAL FIXATION SYSTEM**

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___ AND/OR Over-The-Counter Use **NONE**
(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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052196