JAN 10 2014

510(k) Summary

DigiFix™ External Fixation System

January 9, 2014

Company: Virak Orthopedic Research LLC
115 Fairfield Avenue
Short Hills, NJ 07078 USA
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Establishment Registration: To be completed prior to distribution

Primary Contact: Kimberly Strohkirch
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Company Contact: Dr. Virak Tan, President and CEO

Trade Name: DigiFix™ External Fixation System

Common Name: Smooth or threaded bone fixation fastener

Classification: Class II

Regulation Number: 21 CFR 888.3040

Panel: 87 - Orthopedic

Product Code: JEC, Component, Traction, Invasive

Device Description:

The DigiFix™ External Fixation System includes various elements including brackets, locking pins, set screws and k-wires. The elements are used to create an assembled frame which capture and support the k-wires on the medial and lateral aspect of finger. The brackets, locking pins and set screws are assembled intraoperatively. External fixator components are provided non-sterile and are intended for single use only.

Instrument System
Instruments used with the DigiFix™ External Fixation System include the following: Pin Placement Guide, Bracket Expander, Bracket Pliers, Hex Driver, Wire Bender and Wire Cutter. The instruments are reusable and provided non-sterile.

Indications for Use:

The DIGIFIX™ External Fixation System is intended to be used in skeletally mature patients in treatment of:

DYNAMIC MODE:

1) complex fracture-dislocations or fracture-subluxation, unstable dislocations, and pilon fractures of the interphalangeal (IP) joint;
2) Post-traumatic joint contracture of the proximal interphalangeal (PIP) joint;

STATIC MODE:

1) Fractures of the phalanges and
2) interphalangeal (IP) joint arthrodesis.

Substantial Equivalence:
K094043 – AREX® Ligamentotaxor
K970713 – Smith & Nephew® COMPASS® HINGE External Fixator
K072212 – Smith & Nephew® Jet-X® Bar System Clamps, Bars and Posts - MR Cond
K980370 – BIOMET® BioSymMetric Proximal Interphalangeal Joint Fixator

The intended use, indications for use, material, surgical technique and dimensions of the subject devices are substantially equivalent to the predicate devices.

Performance Testing:
FDA's Guidance for Orthopedic External Devices (2/21/1997) was used as a framework for evaluating the safety and effectiveness of the subject device.

A device which has essentially the same design and materials as the predicate should not require testing unless there is new information which raises safety and effectiveness concerns. The DigiFix™ device utilizes materials and has design features that are the same as the predicate devices. Evaluation of the material, dimensions and K-wires demonstrates that the subject device has a higher estimated rigidity than the predicate devices. Thus, no performance testing is necessary to support substantial equivalence of the device.

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

January 10, 2014

Virak Orthopedic Research, LLC
% Kimberly Strohkirch, MSE
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K132731
Trade/Device Name: DIGIFIX™ External Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JEC
Dated: October 11, 2013
Received: October 15, 2013

Dear Ms. Strohkirch:

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 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. 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 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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K132731

Device Name: DIGIFIX™ External Fixation System

Indications for Use:

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STATIC MODE: 1) comminuted fractures of the phalanges and 2) interphalangeal (IP) joint arthrodesis.

Prescription Use___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices