October 10, 2019

Virak Orthopedics, LLC
% Christine Scifert
Executive Vice President
Mrc-x, LLC
6075 Poplar Ave Suite 500
Memphis, Tennessee 38119

Re: K192465
Trade/Device Name: DigiFix Sterile Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JEC
Dated: September 5, 2019
Received: September 9, 2019

Dear Christine Scifert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192465

Device Name
DIGIFIX External Fixation System Sterile Kit

Indications for Use *(Describe)*
The DIGIFIXTM 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;
3) Dupuytren's contracture

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K192465

510(k) Summary

DIGIFIX™ External Fixation System Sterile Kit

September 5, 2019

Company: Virak Orthopedics, LLC
620 Essex St
Harrison, NJ 07029
901-260-7931

Primary Contact: Christine Scifert

Company Contact: Dr. Virak Tan

Trade Name: DIGIFIX™ External Fixation System Sterile Kit

Common Name: Smooth or threaded metallic bone fixation fastener

Classification: II

Regulation Number: 21 CFR 888.3040

Panel: 87-Orthopedic

Product Code(s): JEC

Device Description: The DigiFix™ External Fixation System Sterile Kit 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 sterile and are intended for single use only.

Indications for Use: The DigiFix™ External Fixation System Sterile Kit 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; 3) Dupuytren's contracture STATIC MODE: 1) Fractures of the phalanges and 2) interphalangeal (IP) joint arthrodesis

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate

- K132731 – DigiFix™ External Fixation System

Performance Testing: A sterilization validation substantiated a minimum 25 kGy gamma radiation dose for sterilizing a single batch of product and demonstrated a Sterility Assurance Level (SAL) of 10^{-6} based on Method VDMax 25, as outlined in ISO 11137-1 and ISO 11137-2 for the Virak DigiFix™ External Fixation System.

A cleaning validation challenged the IPA dipping method to clean the Virak DigiFix™ External Fixation System utilizing 99% Isopropyl Alcohol. An Operational Qualification (OQ) was performed.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.