K192465

510(k) Summary

DIGIFIX™ External Fixation System Sterile Kit

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Company: Virak Orthopedics, LLC
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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.