DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
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*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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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