



Food and Drug Administration
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Silver Spring, MD 20993-0002

Cardinal Health
Ms. Tatyana Bogdan
Director, Regulatory Affairs
1500 Waukegan Road
Waukegan, Illinois 60085

April 29, 2015

Re: K150579

Trade/Device Name: Cardinal Health External Fixation System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: KTT

Dated: March 5, 2015

Received: March 9, 2015

Dear Ms. Bogdan:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K150579

Device Name

Cardinal Health External Fixation System

Indications for Use (Describe)

The Cardinal Health External Fixation System is intended for use to provide treatment for long bone and pelvic fractures that require external fixation.

The system can be used for:

- Stabilization of soft tissues and fractures
- Polytrauma/multiple orthopedic trauma
- Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation
- Non-unions/septic non-unions
- Intra-operative reductions/stabilization tool to assist with indirect reduction
- Unilateral rectilinear bone segment transport or leg lengthening

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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510(k) SUMMARY

510(k) Number: K150579

Submitter's Name, Address, Telephone Number:

Cardinal Health
1500 Waukegan Road
Waukegan IL 60085

Contact Person:

Tatyana Bogdan
Director, Regulatory Affairs
Phone: 847.887.2325
Facsimile: 847.785.2461
Email: tatyana.bogdan-curvin@cardinalhealth.com

Prepared by:

Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: March 5, 2015

Device Name: Cardinal Health External Fixation System

Device Classification:

Class II; 21 CFR 888.3030

Classification Name:

Single/multiple component metallic bone fixation appliances and accessories

Product Code:

KTT

Device Description:

The Cardinal Health External Fixation System consists of rod-to pin clamps, rod-to-rod clamps, rods, pins, Schanz screws and associated instruments for site preparation and implant insertion. All components intended to be attached to bone are fabricated from medical grade stainless steel (316L Stainless Steel per ASTM F138). External clamps are fabricated from Titanium Alloy (Ti-6Al-4V-ELI per ASTM F136), and radiolucent external fixation rods are fabricated from carbon fiber reinforced epoxy. The Cardinal Health External Fixation System is provided non-sterile.

Indications for Use:

The Cardinal Health External Fixation is intended for use to provide treatment for long bone

and pelvic fractures that require external fixation.

The system can be used for:

- Stabilization of soft tissues and fractures
- Polytrauma/multiple orthopedic trauma
- Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation Non-unions/septic non-unions
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- Unilateral rectilinear bone segment transport or leg lengthening

Predicate Device:

Emerge External Fixation System (K140675)

Performance Data:

Testing was performed on the Cardinal Health External Fixation System in accordance with ASTM F2182–11a, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, ASTM F2052-06, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment, and ASTM F2213-11, Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment. Results demonstrate that the Cardinal Health External Fixation System is safe and compatible in the MR environment as an “MR Conditional” device. The predicate 510(k), K140675, included performance testing conducted per ASTM F1541-02 (2001). In all instances, the External Fixation System met acceptance criteria, functioned as intended and performed as well as the predicate device.

Substantial Equivalence:

The Cardinal Health External Fixation System is substantially equivalent to the legally marketed predicate based on intended use, basic design, materials, sizing and performance.