

XtraFix External Fixation System
K111155
510(k) Summary

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Device Manufacturer: ExtraOrtho, Inc.
8275 Tournament Drive, Suite 160
Memphis, TN 38125

Submission Date: October 20, 2011

Contact Person: Steve Miller
Tel: 1-901-748-2581
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Proprietary Name: XtraFix External Fixation System

Common Name: External Fixation Frame Components

Classification regulation: 888.3030 Single/multiple component metallic bone fixation appliances and accessories, 888.3040 Smooth or threaded metallic bone fixation fastener

Device Class: Class II

Product Codes: KTT and JDW/ Orthopedics/87

Device Description and Intended Use:

The XtraFix External Fixation System includes various elements designed to build a fixator construct. The system includes clamps, posts, bars, and fixation pins.

The XtraFix External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (foot, femur, and tibia) and pelvic fractures that require external fixation. Specifically, the system is intended for:

- Temporary stabilization of open or closed acute fractures with soft tissue injuries;
- Definitive stabilization of open or closed fractures where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Stabilization of fractures in the context of polytrauma;
- Temporary or definitive stabilization of certain pelvic fractures or pelvic ring injuries;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint (knee, and ankle) arthroplasty for infection or other failure;
- Neutralization of fractures stabilized with limited internal fixation;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization tool to assist with indirect reduction.

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Predicate Devices:

The XtraFix External Fixation System is similar to several predicates including the following:

- ExtraOrtho XtraFix External Fixation System (K091258);
- Stryker Hoffmann II MRI External Fixation System (K053472);
- Synthes Large External Fixation Clamps- MR S (K082650); and
- Smith & Nephew Jet-X Unilateral Fixator (K072212).

Technological Characteristics

The principles of operation of the XtraFix External Fixation System are the same as for the predicates. The XtraFix External Fixation System was characterized and evaluated according to the requirements outlined in FDA Guidance document, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment." Testing confirmed the device can be used in an MR environment under predetermined conditions. Therefore, the term "MR Conditional" can be used to describe the system in accordance with the guidance document.

Substantial Equivalence Information:

The XtraFix External Fixation System is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the XtraFix External Fixation System is substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Extraortho, Inc.
% Mr. Marcos Velez-Duran
901 King Street, Suite 200
Alexandria, Virginia 22314

OCT 20 2011

Re: K111155

Trade/Device Name: XtraFix Extrnal 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, JDW

Dated: September 29, 2011

Received: September 30, 2011

Dear Mr. Velez-Duran:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,


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

Enclosure

Indications for Use Statement

510(k) Number: To be assigned K111155
Device Name: Xtrafix External Fixation System

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- Intraoperative temporary stabilization tool to assist with indirect reduction.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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