K101375

510(K) Summary of Safety and Effectiveness

TRIMED X-FIX SYSTEM

SEP 15 2010

Submitted By:	TriMed, Inc. 25864 Tournament Road, Ste. A Valencia, CA 91355 (800)633-7221
Registration #:	2031009
Prepared By/Contact Person:	Kelli Anderson Phone: (661)312-7150 Fax: (661)254-8485
Proprietary Name:	X-Fix System
Classification:	Class II: Smooth or Threaded Metallic Bone Fixation Fastener NDK - Section 888.3040
Summary Preparation Date:	September 13, 2010

I. Indications for Use:

The TriMed X-Fix System is a unilateral external fixation device. It is intended to be used in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality.

II. Device Description:

The X-Fix System is a unilateral external fixation device. It includes various size components to accommodate various anatomies and injuries. The pin clamps enable the frame to be coupled to bone by securing the pins for the intended use.

The X-Fix System is made of aluminum, black carbon composite and F-138 surgical grade stainless steel.

III. Substantial Equivalence:

The TriMed X-Fix System has been compared to the Avanta Orthopaedics External Fixator (K974911/K981716). The X-Fix is equivalent in dimensions, design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

TriMed, Inc.
% Ms. Kelli Anderson
25864 Tournament Road, Suite A
Valencia, California 91355

SEP 15 2010

Re: K101375
Trade/Device Name: X-Fix System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: II
Product Code: NDK
Dated: August 11, 2010
Received: August 12, 2010

Dear Ms. Anderson

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" (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 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,

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

510(k) Number (if known): ~~Unknown~~ K101375

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Device Name: X-Fix

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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

510(k) Number K101375