JAN 2 1 2005

K043113

510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Claudia S. Swanson** Sr. Regulatory Specialist Phone: 574.371.4989 FAX: 574.371.4987
Trade Name:	**TempFix™ External Fixation System, MR Safe**
Common Name:	External Fixation Devices
Classification:	Class II per 21 CFR 888.3030: Multiple component metallic bone fixation appliances and accessories
Device Product Codes:	**87 KTT**

Substantially Equivalent Devices:

TempFix™ External Fixation System (predicate device)	K021933
Synthes Medium External Fixation System (for MR safety)	K011034
EBI® DynaFix®Vision ™External Fixation System (for MR safety)	K961433

Device Description:
The TempFix External Fixation System consists of components that can be assembled to provide multiple degrees of freedom for positioning implantable threaded fixation pins on either side of a fracture or deformity. The unique frame materials provide radiolucent viewing of the fracture and are lightweight for patient comfort. The components are pre-assembled in kits with three basic frame configurations: a knee frame, a half pin ankle frame, a 400 mm bar, and a transfixing pin ankle frame. Each kit is provided in sterile and non-sterile versions.

Indications for use:
The TempFix External Fixation System is indicated for: external fixation of open or closed long bone fractures and correction of bony or soft tissue defects or deformities.

When used without adjunctive support, the TempFix External Fixation System is intended to be non-weight bearing.

DePuy is seeking the following additional claim:

The TempFix External Fixation System is MR safe when specific guidelines are followed relative to the use of 1.5-Tesla MR systems, **only.**

Substantial equivalence:
The TempFix™ External Fixation System was originally cleared via K021933.

DePuy is seeking additional claims for MR safety based on the conformance of the material to the standards included in Section I under E. Materials. Other comparable devices cleared for MR safety are the Synthes Medium External Fixation System (K011034), and the Biomet EBI® DynaFix®Vision™External Fixation System (K961433).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2005

Ms. Claudia S. Swanson
Sr. Regulatory Specialist
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581

Re: K043113
Trade/Device Name: TempFix External Fixation System, MR Safe
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: November 8, 2004
Received: November 10, 2004

Dear Ms. Swanson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: TempFix External Fixation System, MR Safe

Indications for Use:

Existing indications cleared in K021933:

The TempFix External Fixation System is indicated for external fixation of open or closed long bone fractures and correction of bony or soft tissue defects or deformities.

When used without adjunctive support, the TempFix External Fixation System is intended to be non-weight bearing.

DePuy also seeks the following additional indications:

The TempFix External Fixation System is MR safe when specific safety guidelines are followed relative to the use of 1.5-Tesla MR systems, **only.**

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043113

Prescription Use_____X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)