AUG 26 2002

510(k) Summary

Name of Sponsor:	DePuy ACE 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	Cheryl K. Hastings Director, Regulatory Affairs Phone: (574) 372-7006 FAX: (574) 371-4987
Trade Name:	TempFix™ External Fixation System
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 ; LXT

Substantially Equivalent Devices:

Howmedica Osteonics Hoffman II External Fixator	K000957
Immedica Transfx External Fixation System (distributed by Zimmer)	K984357
ACE Medical Company Align Fixator	K936045
ACE Medical Company ACE –Fischer Pins	K875022 K875012
ACE Medical Company ACE-DuPont Composite Rings	K955388

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 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 of the distal femur, proximal tibia or distal tibia where soft tissue injury precludes the use of other fracture treatments.

The TempFix External Fixation System is intended to be non-weight bearing.

Substantial equivalence:
The TempFix External Fixation System is a lightweight external fixation system similar in intended use and design to the Howmedica Osteonics Hoffman II External Fixator, the Immedica Transfx External Fixation System (distributed by Zimmer) and the DePuy ACE Align Fixator. The implantable stainless steel pins are identical to those cleared previously for the ACE-Fischer Fixator with the exception that the TempFix pins will be etched with positioning lines to provide the surgeon a tool for measuring the insertion depth of the pin. The bar assemblies included in each kit and the U-ring included in the ankle transfixing pin kit are manufactured from carbon fiber / resin composite material as previously cleared for the ACE-DuPont Composite Rings. The articulating slide end and articulating clamp ends used in the TempFix System are similar to those cleared for the ACE Align Fixator. When tested to simulate clinical use, the TempFix constructs were stiffer and had a higher load to failure than either the Howmedica Hoffman II constructs or the Immedica / Zimmer Transfx constructs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Ms. Cheryl Hastings
Director, Regulatory Affairs
DePuy ACE
P. O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K021933

Trade Name:	TempFix™ 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, LXT
Dated:	June 11, 2002
Received:	June 12, 2002

Dear Ms. Hastings:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

510(k) Number (if known): K021933

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The TempFix External Fixation System is intended to be non-weight bearing.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhous

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

510(k) Number K021933

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