K013430

DEC 1 7 2001

510(k) Summary

Name of Sponsor:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact:

Marcia J. Arentz
Senior Regulatory Associate
Phone: (219) 371-4944
FAX: (219) 371-4987

Trade Name:

ACE BioWin Tibial Nailing System

Common Name:

Bone fixation device

Classification:

Class II Device per 21 CFR 888.3020
Intramedullary fixation rod
Description: Rod, Fixation, Intramedullary and Accessories, Metallic and Non-collapsible

Device Product Code:

Code: **87HSB**
No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for intramedullary nails or bone fixation fasteners.

Substantially Equivalent Device:

ACE AIM Tibial Nail	K972183
Synthes AO Nail	K914453
Biomet LactoSorb® 5.0mm washer	K001581

Device Descriptions:

The BioWin Tibial Nailing System consists of an intramedullary nail, cortical screws, end cap, and an optional bioresorbable window. The nails, screws and end cap are all manufactured from Titanium (Ti-6Al-4V ELI) and the optional bioresorbable window is made from a lactide/glycolide copolymer.

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510(k) Summary (continued)

Indications for use:

The BioWin Tibial Nailing System is indicated in reamed and unreamed applications for internal fixation of tibial fractures, including transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, fractures with bone loss, bone transport, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions, metaphyseal fractures and epiphyseal fractures.

Substantial equivalence:

The BioWin Tibial Nailing System has the same intended use and has the same general design features as the ACE AIM Tibial Nail and the Synthes AO nail and is therefore substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 7 2001

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopedic, Inc.
700 Orthopedic Drive
P.O. Box 988
Warsaw, Indiana 46581

Re: K013430
Trade/Device Name: Bio™Win Tibial Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 15, 2001
Received: October 16, 2001

Dear Ms. Arentz:

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/dsma/dsmamain.html

Sincerely yours,

for 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): K013430

Device Name: BioWin™ Tibial Nailing System

Indications for Use:

The ACE BioWin Tibial Nailing System is indicated in reamed and unreamed applications for internal fixation of tibial fractures including transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, fractures with bone loss, bone transport, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions, metaphyseal fractures and epiphyseal fractures.

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

510(k) Number K013430

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use No