DEC 18 1998

K983906

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive; P.O. Box 988
Warsaw, Indiana 46581-0988

510(k) CONTACT:

Sally Foust
Sr. Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
(219) 372-7455; FAX 1 (219) 267-7098
E-mail: Sally_Foust@ccgate.depuy.com

TRADE NAME:

DePuy OrthoTech Spiked Washer

COMMON NAME:

Spiked Washer

CLASSIFICATION:

888.03030 - Single/multiple component, metallic bone fixation appliances and accessories

DEVICE PRODUCT CODE:

87 HTN, HWC

SUBSTANTIALLY EQUIVALENT DEVICES:

Smith-Nephew Acufex® Tibial Anchor Screw & Spiked Washer (K961649)
Synthes® Spiked Washer (K914472)

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy OrthoTech Spiked Washer is a circular device with eight inferior (fixative surface) spikes and a central hole for screw insertion. The DePuy OrthoTech Spiked Washer is manufactured from polyacetal polymer and is available in two outer diameters, 8mm and 13.5mm.

The DePuy OrthoTech Spiked Washer is intended for use with a 6.5mm cancellous thread or a 4.5mm cortical thread low profile head screw for fixation of soft tissue, such as tendon and ligaments, to bone in orthopaedic procedures.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy OrthoTech Spiked Washer is substantially equivalent to both the Smith & Nephew Acufex Spiked Washer and the Synthes Spiked Washer in that all are circular washers designed with fixative surface spikes, are manufactured from polyacetal polymer, and are intended for use with screws for fixation of soft tissue, such as tendon and ligaments, to bone in orthopaedic procedures.

Based on similarities of design, materials and intended use, DePuy believes that the subject spiked washer is substantially equivalent to the previously cleared Smith & Nephew Acufex Tibial Spiked Washer and Synthes Spiked Washer.

The table on the following page summarizes the similarities:

	DePuy OrthoTech Spiked Washer (Current)	Acufex® Tibial Anchor Screw & Spiked Washer (K961649)	Synthes (USA) Spiked Washer (K914472)
MATERIAL	**Polyacetal Polymer**	**Polyacetal Polymer**	**Polyacetal Polymer**
IINTENDED USE	Soft Tissue Fixation	Soft Tissue Fixation	Ligament Fixation
PRODUCT CODE	HTN HWC	HWC	HTN
USE WITH SCREWS	Yes	Yes	Yes
WASHER DESIGN	Circular With Spikes	Circular With Spikes	Circular With Spikes
WASHER OUTER DIAMETER	8mm 13.5mm	14-20mm	13.5mm
LABELING	Non-Sterile, Single Use	Sterile, Single Use	Sterile, Single Use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

Ms. Sally Foust
Senior Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K983906
Trade Name: DePuy OrthoTech Spiked Washer
Regulatory Class: II
Product Code: HWC
Dated: November 2, 1998
Received: November 3, 1998

Dear Ms. Foust:

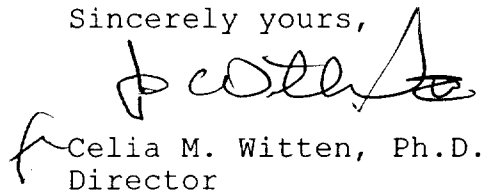
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



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) K963906

Device Name DePuy OrthoTech Spiked Washer

Indications for Use:

The DePuy OrthoTech Spiked Washer is intended for use with a 6.5mm cancellous thread or a 4.5mm cortical thread low profile head screw for fixation of soft tissue, such as tendon and ligaments, to bone in orthopaedic procedures.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use __X__ OR Over-The Counter Use __

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963906