K982900 mxm 8/27/98

AUG 31 1998

SPECIAL 510(k) DEVICE MODIFICATION
PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF SPONSOR:

DePuy®, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

510(k) CONTACT:

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

TRADE NAME: Phantom™ SofThread Soft Tissue Interference Screw

COMMON NAME: Interference Screw

CLASSIFICATION: 888.3040 - Smooth or threaded bone fixation fastener

DEVICE PRODUCT CODE: 87 HWC

SUBSTANTIALLY EQUIVALENT DEVICE:

Phantom SofThread Soft Tissue Interference Screw
(K980440)

DEVICE DESCRIPTION AND INTENDED USE:

The modified Phantom SofThread Screw is a resorbable, cannulated, interference screw with widely spaced, rounded threads and a conical tip, designed for use with soft tissue grafts. The SofThread Screw is available in four diameters (7, 8, 9 and 10mm) in one 25mm length. The modified Phantom SofThread Screw is intended to be used to provide interference fixation of soft tissue grafts in ACL reconstruction.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The fundamental scientific technology of the modified Phantom SofThread Screw has not changed from the FDA cleared (K980440) Phantom SofThread Screw. The intended use of the modified Phantom SofThread Screw as described in its labeling has not changed from the FDA cleared (K980440) Phantom SofThread Screw. With the exception of minor design modifications (i.e., rounded head; increased broach depth, nose diameter and minor diameter, and slightly reduced thread pitch) the modified Phantom SofThread Screw is identical to the FDA cleared (K980440) Phantom SofThread Screw.

Based on conformance with the design control procedures requirements as specified in 21 CFR 820.30, similarities of design, identical materials and intended use, DePuy believes that the modified Phantom SofThread Screw is substantially equivalent to the FDA cleared K980440) Phantom SofThread Screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1998

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

Re: K982900
Trade Name: Phantom™ SoftThread Soft Tissue Interference Screw
Regulatory Class: II
Product Codes: MAI and HWC
Dated: August 14, 1998
Received: August 17, 1998

Dear Ms. Foust:

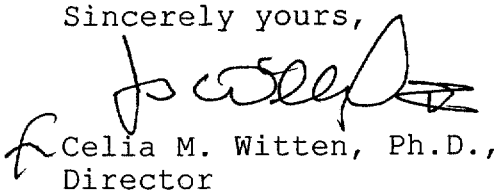
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) K982900

MXM
8/27/98

Device Name: Phantom SofThread Soft Tissue Interference Screw

Indications for Use:

The Phantom SofThread Soft Tissue Interference Screw is intended to be used to provide interference fixation of soft tissue grafts in ACL reconstruction.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982900

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)