

K980440

APR - 3 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF SPONSOR: DePuy Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

510(k) CONTACT: Cheryl Hastings
Manager, Regulatory Submissions

TRADE NAME: DePuy OrthoTech Phantom™ Sof-Thread Soft Tissue Interference Screw

COMMON NAME: Interference Screw

CLASSIFICATION: 888.3040 Smooth or threaded bone fixation fastener

DEVICE PRODUCT CODE: 87 HWC

SUBSTANTIALLY EQUIVALENT DEVICES:
DePuy Hyloc Interference Screw, K955733
Linvatec BioScrew Absorbable Interference Screw, K960652

DEVICE DESCRIPTION AND INTENDED USE:

The Phantom Sof-Thread Screw is a resorbable, cannulated, interference screw with widely spaced, rounded threads and a conical tip, designed for use with soft tissue grafts. The Sof-Thread Screw is available in 4 diameters, 7, 8, 9 and 10mm, and one length, 25mm. The Phantom Sof-Thread Screw is intended to be used to provide interference fixation of soft tissue grafts in ACL reconstruction.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Hyloc Interference Screw (now called the Phantom Interference Screw) is a resorbable, cannulated or non-cannulated interference screw, manufactured from the same material as the Phantom Sof-Thread Screw (PLLA), available in diameters of 7, 8 and 9mm and in lengths of 15-30mm. It is intended to be used to provide interference fixation of the bone block in bone-tendon-bone grafts used for ACL reconstruction. The major differences in design between the Phantom Sof-Thread Screw and the Phantom Interference Screw are the more rounded and widely spaced threads, the rounded edges on the driver end and the one larger diameter size of the Phantom Sof-Thread Screw.

The Linvatec BioScrew Absorbable Interference Screw is a resorbable, cannulated interference screw available in diameters of 7-9mm and lengths of 20-30mm. The BioScrew is manufactured from PLLA and is intended "to provide interference fixation of patellar bone-tendon-bone grafts in ACL reconstruction and for femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft (semitendinous, gracilis)".

Mechanical testing in cadaver bone has shown that the average insertion torque and pull-out strength of the Phantom Sof-Thread Screw are comparable to those of the Linvatec BioScrew.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Cheryl Hastings
Manager, Regulatory Submissions
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedics Drive
Warsaw, Indiana 46581-0988

Re: K980440
Trade Name: Phantom™ Sof-Thread Soft Tissue Interference Screw
Regulatory Class: II
Product Code: HWC and MAI
Dated: February 3, 1998
Received: February 4, 1998

Dear Ms. Hastings:

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.

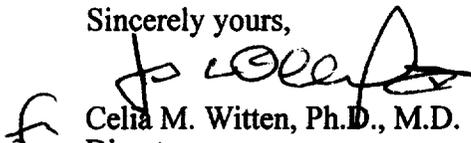
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 at (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) K980440

Device Name Phantom Sof-Thread Soft Tissue Interference Screw

Indications for Use:

The Phantom Sof-Thread 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

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

[Signature]
(Division Sign-off)
Division of General Restorative Devices

510(k) Number

K980440

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