

OCT 28 1998

K982662

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

FIRM CONTACT: Sally Foust
Senior Regulatory Submissions Associate

TRADE NAME: DePuy Profile™ Round Head Interference Screw
DePuy Phantom™ Resorbable Interference Screw

COMMON NAME: Bone Screw

CLASSIFICATION: 888.3040 Smooth or threaded metallic bone fixation fastener

DEVICE PRODUCT CODE: 87 HWC and MAI

SUBSTANTIALLY EQUIVALENT DEVICES:

- DePuy Phantom Absorbable Interference Screw (K955733, K981670)
- DePuy Profile Round Head Interference Screw (K961234, K981670)
- Linvatec BioScrew Absorbable Interference Screw (K960652, K960940)

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Interference Screw Systems are cannulated fully threaded cancellous bone screws available in three diameters (7, 8, and 9mm) in three lengths (20, 25, and 30mm), and manufactured from titanium alloy (DePuy Profile Round Head Interference Screw) and from Poly-L-lactic acid (DePuy Phantom Absorbable Interference Screw).

The DePuy Interference Screw Systems are intended to provide interference fixation of bone-patellar tendon-bone grafts in ACL and PCL reconstruction and of soft tissue grafts in ACL reconstruction.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Profile Round Head and the Phantom Absorbable Interference Screws are identical in design and materials to the DePuy Profile Round Head and Phantom Absorbable Interference screws which have been previously cleared by FDA for interference fixation of bone-patellar tendon-bone grafts in ACL reconstruction and of soft tissue grafts in ACL reconstruction. The only difference between this submission and the previously cleared submission is the additional indication for interference fixation of bone-patellar tendon-bone grafts in PCL reconstruction.

Mechanical testing has shown that the mean pull-out loads of the Profile Round Head Interference Screws and the Phantom Absorbable Interference Screws are comparable to those published for the previously cleared Linvatec BioScrew indicated for interference fixation in PCL reconstruction.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982662
Trade Name: DePuy Profile Round Head Interference Screw
and DePuy Phantom Interference Screw
Regulatory Class: II
Product Codes: HWC, MBI, and MAI
Dated: July 29, 1998
Received: July 30, 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.

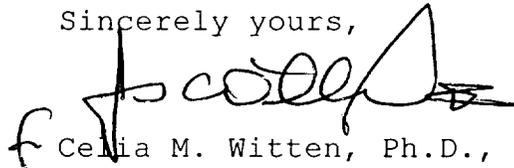
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized initial 'C' and a horizontal line extending to the right.

f 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

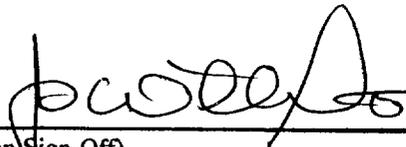
510(k) Number (if known) K982662

Device Name DePuy Interference Screw Systems - Additional Indication/Intended Use to Provide Interference Fixation of Bone-Patellar Tendon-Bone Grafts in Posterior Cruciate Ligament (PCL) Reconstruction

Indications for Use:

The DePuy Interference Screw Systems are intended to be used to provide interference fixation of bone-patellar tendon-bone grafts in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction and 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 K982662

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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