

JUN 22 1998

K981670

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  
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

**SUBSTANTIALLY EQUIVALENT DEVICES:**

- DePuy Advantage Fixation Screw System (K961234)
- DePuy Hyloc Interference Screw (K955733)
- DePuy Phantom SofThread Soft Tissue Interference Screw (K980440)
- Linvatec BioScrew Absorbable Interference Screw (K960652, K960940)
- Smith & Nephew Donjoy RCI Screw (K945687)

**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 anterior cruciate ligament (ACL) 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 similar in design and materials to the DePuy Advantage and Hyloc Interference screws which have been previously been cleared by FDA for interference fixation of bone-patellar tendon-bone grafts in ACL reconstruction. Aside from minor design changes and fewer screw length options, the only difference between this submission and the previously cleared submissions is the additional indication for interference fixation of soft tissue grafts in ACL reconstruction.

Mechanical testing in cadaver bone has shown that the average insertion torque and pull-out strength of the Profile Round Head Interference Screws and the Phantom Absorbable Interference Screws are comparable to those of the previously cleared DePuy SofThread Soft Tissue Interference Screw and Linvatec BioScrew indicated for interference fixation of soft tissue grafts in ACL reconstruction.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K981670  
Trade Name: DePuy Profile Round Head Interference Screw  
DePuy Phantom Resorbable Interference Screw  
Regulatory Class: II  
Product Codes: HWC and MAI  
Dated: May 11, 1998  
Received: May 12, 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.

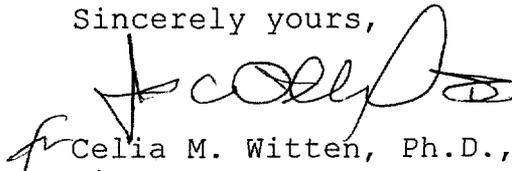
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Sally Foust

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". The signature is fluid and cursive, with a large initial "C" and "W".

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) K981670

Device Name DePuy Interference Screw Systems - Additional Indication/Intended Use

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) reconstruction and of soft tissue grafts in ACL reconstruction.

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Concurrence of CDRH, Office of Device Evaluation

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K981670

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

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