

**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  
Clinical Affairs Associate  
(219) 372-7455  
FAX (219) 267-7098  
e-mail: Sally\_Foust@ccgate.depuy.com

**TRADE NAME:** DePuy DuPont Absorbable Set Screw  
**COMMON NAME:** Bone/Tendon/Bone Screw  
**CLASSIFICATION:** 888.3040 Smooth or threaded bone fixation fastener  
**DEVICE PRODUCT CODE:** 87 HWQ

**SUBSTANTIALLY EQUIVALENT DEVICES:** Hyloc™ Interference Screw (DePuy DuPont)  
DePuy Set Screw  
M. Kurosaka Interference Screw (DePuy)  
DePuy Advantage Fixation Screw System

**DEVICE DESCRIPTION AND INTENDED USE:** The DePuy DuPont Absorbable Set Screw is a fully threaded, cannulated, headless cancellous bone screw with a blunt tip. It is manufactured from poly-L-lactic acid (PLLA) and is available in a 9.0mm diameter in seven lengths (20, 25, 30, 35, 40, 45, and 50mm).

The DePuy DuPont Absorbable Set Screw is intended to provide early fixation of the bone block in bone-patellar-tendon-bone graft in anterior cruciate ligament (ACL) reconstruction. The screw is inserted by a square headed drive which is broached into the minor diameter of the screw body. The screw is used to compress the bone block against the wall of the bone tunnel and secure the ACL graft. The screw is gradually resorbed by the body.

**BASIS OF SUBSTANTIAL EQUIVALENCE:** The DePuy DuPont Absorbable Set Screw, Hyloc Interference Screw, DePuy Set Screw, M. Kurosaka Interference Screw, and the DePuy Advantage Fixation Screw System are all intended to provide early fixation of the bone block in bone-patellar-tendon-bone graft fixation in anterior cruciate ligament (ACL) reconstruction, and employ the same principles of graft fixation. All of the substantially equivalent devices are fully threaded, cannulated, headless designs available in a diameter of 9mm. The DePuy DuPont Absorbable Set Screw and the Hyloc Interference Screw are both manufactured from poly-L-lactic acid (PLLA) with the same specifications and obtained from the same supplier, and are implanted with a square driver, while the DePuy Set Screw, M. Kurosaka Interference Screw, and the DePuy Advantage Fixation Screw System are manufactured from titanium and are implanted with a hex driver. The DePuy DuPont Absorbable Set Screw, the Hyloc Interference Screw, and the DePuy Set Screw all have a blunt tip, while the M. Kurosaka Interference Screw has a pointed tip and the DePuy Advantage Fixation Screw System has a tapered tip. The DePuy DuPont Absorbable Set Screw, the Advantage Interference Screw and the DePuy Set Screw have the same thread form and pitch. The DePuy DuPont Absorbable Set Screw and the DePuy Set Screw are available in exactly the same lengths (20, 25, 30, 35, 40, 45, and 50mm).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 1 1997

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

Re: K972494  
DePuy DuPont Absorbable Set Screw  
Regulatory Class: II  
Product Code: HWC  
Dated: July 2, 1997  
Received: July 3, 1997

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

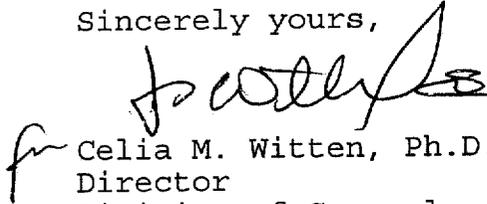
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



*for* 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) K972494

Device Name DePuy DuPont Absorbable Set Screw

Indications for Use:

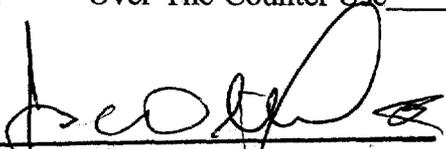
The DePuy DuPont Absorbable Set Screw is intended to provide early fixation of the bone block in bone-patellar-tendon-bone graft in anterior cruciate ligament reconstruction.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use X  
(Per 21 CFR 801.109)

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

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

510(k) Number \_\_\_\_\_

K972494

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