JUN - 9 1997 K970929

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

FIRM CONTACT:

Sally Foust
Clinical Affairs Associate
(219) 372-7455
E-Mail: Sally_Foust@ccgate,depuy.com

TRADE NAME: DePuy Low Profile Bone Screw

COMMON NAME: Bone Screw

CLASSIFICATION: 888.3040 Smooth or threaded metallic bone fixation fastener

DEVICE PRODUCT CODE: 87 HWC

SUBSTANTIALLY EQUIVALENT DEVICES:
Depuy Stainless Steel Bone Screws- pre-1976

DEVICE DESCRIPTION AND INTENDED USE:
The DePuy Low Profile Bone Screws, manufactured in both titanium and cobalt-chrome, are manufactured in eleven lengths (15, 20, 25, 30, 35, 40, 45, 50, 55, 60 and 65mm) with a 6.5mm major diameter. The head of the screw is designed with a "low profile" to allow the head to be placed below the surface of the device being fixed. An internal hex fitting in the head is used for instrument (a hex drive) insertion of the screw during surgery. The distal two-thirds of the screw is coarsely threaded while the proximal one-third is smooth with a polished satin finish. The screw has a distal flute to aid in insertion into cancellous bone. The DePuy Low Profile Bone Screw is indicated for use as an ancillary fixation device to be used with tibial and acetabular components in total knee and hip arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Except for the larger major diameter, change in manufacturing material (from stainless steel to either titanium or cobalt-chrome alloys) and the restriction of the intended use to an ancillary fixation device to be used with tibial and acetabular components in total knee and hip arthroplasty, the DePuy Low Profile Bone Screws are substantially equivalent to the pre-1976 DePuy stainless steel bone screws indicated for general use in fracture fixation and bone reconstruction. All are manufactured in various lengths to accommodate patient bone structure and surgeon preference. All are designed with a distal flute to aid in insertion into cancellous bone. Based on the information provided in this premarket notfication, DePuy considers the DePuy Low Profile Bone Screws to be substantially equivalent to specified pre-1976 fixation screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 1997

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

Re: K970929
Low Profile Bone Screws
Regulatory Class: II
Product Code: HWC
Dated: March 12, 1997
Received: March 13, 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

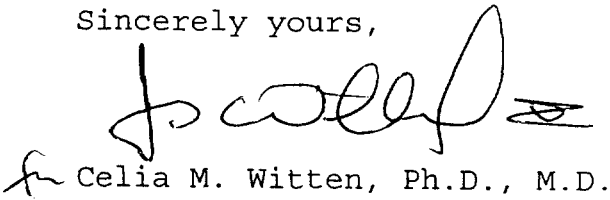
2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm * and overall lengths of 10 mm - 75 mm inclusively, the package insert must include 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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) K970929

Device Name DePuy Low Profile Bone Screw

Indications for Use:

The DePuy Low Profile Bone Screw is indicated for use as an ancillary fixation device to be used with tibial and acetabular components in total knee and hip arthroplasty.

Concurrence of CDRH, Office of Device Evaluation

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970929