

K972629  
510(k) SUMMARY



OCT - 9 1997

**NAME OF FIRM:** DePuy ACE Medical Company  
2260 East El Segundo Boulevard  
El Segundo, CA 90245

**510(k) CONTACT PERSON:** Kathleen Dragovich  
Regulatory Affairs Specialist  
DePuy ACE Medical Company

**TRADE NAME:** DePuy ACE TK2 Hip Screw System

**COMMON NAME:** Compression Hip Screw

**CLASSIFICATION:** 888.3030 Single/multiple component metallic bone fixation appliances and accessories

**DEVICE CODE:** 87LXT

**SUBSTANTIALLY EQUIVALENT DEVICE:** Synthes Dynamic Hip Screw (DHS) System and DePuy ACE Select Lock Hip Screw System

**INTENDED USE:**

The DePuy ACE TK2 Hip Screw System is indicated for fractures of the proximal femur extending from the subcapital area to the level of the lesser trochanter, as well as proximal femoral osteotomies. Appropriate utilization of this device ultimately depends on the surgical judgement surrounding each patient's particular situation.

**DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:**

The TK2 Hip Screw System will be a fixed-angle plate with the option to be rotationally locked or unlocked. The system will offer two lag screws: one with external keys to rotationally "lock," and the other without keys. The design will allow the lag screw assembly to slide within the barrel to ensure continuous compaction of the fracture sight, transfer of the load to the bone instead of the implant, and reduce the risk of acetabular penetration.

The plates will initially be offered in 2 through 14 hole lengths. The plate will be offered in all lengths in 130°, 135°, 140°, 145°, and 150°; and in a short barrel and standard barrel lengths. The lag screws will initially be offered in a keyed and keyless version in lengths from 50mm through 140mm. The lag screws will be offered in a super and standard thread form.

The DePuy ACE TK2 Hip Screw System is similar in design to the Synthes Dynamic Hip System (510k approval K791619) and the DePuy ACE Select Lock Hip Screw System (regulatory assessment approval based on K861178 released 4/15/86), which are indicated for fractures of the proximal femur extending from the subcapital area to the level of the lesser trochanter, as well as proximal femoral osteotomies

Based on the above information, DePuy ACE Medical Company firmly believes that the new DePuy ACE TK2 Hip Screw System is substantially equivalent to the Synthes Dynamic Hip Screw System and the DePuy ACE Select Lock Hip Screw System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kathleen A. Dragovich  
Regulatory Affairs Specialist  
DePuy, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

OCT - 9 1997

Re: K972629  
Trade Name: DePuy Ace TK2 Hip Screw System  
Regulatory Class: II  
Product Code: KTT  
Dated: July 11, 1997  
Received: July 14, 1997

Dear Ms. Dragovich:

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.

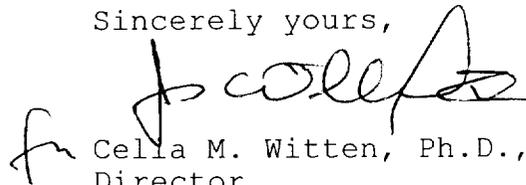
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



fn Cella 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) K972629

Device Name: **DePuy ACE TK2 Hip Screw System**

Indications For Use:

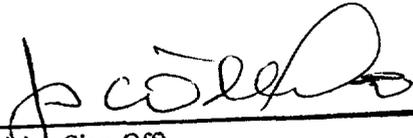
The DePuy ACE TK2 Hip Screw System is indicated for fractures of the proximal femur extending from the subcapital area to the level of the lesser trochanter, as well as proximal femoral osteotomies. Appropriate utilization of this device ultimately depends on the surgical judgement surrounding each patient's particular situation.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X  
(Per 21 CFR 801.109)

OR

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K972629

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