

MAY 22 1998

K974245



**510(k) SUMMARY**

**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 Ring Skull Pin - MRI  
DePuy ACE Spring Loaded Skull Pin - MRI  
DePuy ACE Fixed Tip Tong Pin - MRI

**COMMON NAME:** Pins

**CLASSIFICATION:** 888.3030 Single/Multiple Component Metallic  
Bone Fixation Appliances and Accessories

**DEVICE CODE:** 87LXT

**SUBSTANTIALLY EQUIVALENT DEVICE:** DePuy ACE Standard Skull Pin  
DePuy ACE Spring Loaded (Trippi-Wells) Skull Pin  
DePuy ACE Fixed Tip Tong

**INTENDED USE:**

Pins, when used in conjunction with the DePuy ACE Trippi-Wells Tong, DePuy ACE Standard Tong, DePuy ACE Universal Tong, or Open and Closed Back Halo Rings, may be used for stabilization of the cervical spine in stationary and mobile traction following:

- Cervical fractures
- Ligamentous injury of the cervical spine
- Fusion or other surgery of the cervical spine

**DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:**

The skull pins, which pass through the halo ring or tong, are the only invasive component of the DePuy ACE cervical traction device. The new skull pins, ring and tong (fixed tip and spring loaded), now include a zirconia insert between the pin body and the pin tip. The zirconia insert eliminates the possibility of an electrical current passing to the patient which may cause a burning sensation at the pin insertion points.

The DePuy ACE Ring Skull Pin - MRI is similar in design and indications for use to the DePuy ACE Standard Skull Pin, a preamendment device. The DePuy ACE Spring Loaded Tong Pin - MRI and the DePuy ACE Fixed Tip Tong Pin - MRI are similar in design and indications for use to the DePuy ACE Spring Loaded (Trippi-Wells) Skull Pin, which received approval under 510(k) K810193A.

Based on the above information, DePuy ACE Medical Company firmly believes that the new skull pins are substantially equivalent to the previously approved versions.



MAY 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Paul Doner  
Director Regulatory and Clinical Affairs  
DePuy ACE Medical Company  
2260 East El Segundo Boulevard  
El Segundo, California 90245

Re: K974245  
DePuy ACE Ring Skull Pins, Loaded Tongs, and  
Fixed Tongs - MRI Compatible  
Dated: March 10, 1998  
Received: March 11, 1998

Dear Mr. Doner:

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.

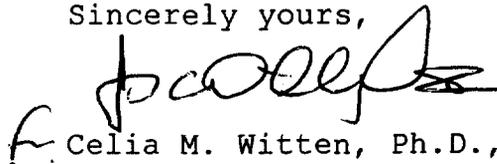
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,



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) K 9 7 4 2 4 5

Device Name: DePuy ACE Ring Skull Pins - MRI  
DePuy ACE Spring Loaded Tong Pin - MRI  
DePuy ACE Fixed Tip Tong Pin - MRI

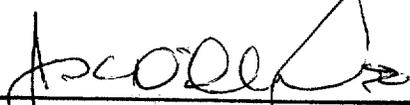
Indication for User:

Pins, when used in conjunction with the DePuy ACE Trippi-Wells Tong, DePuy ACE Standard Tong, DePuy ACE Universal Tong, or Open and Closed Back Halo Rings, may be used for stabilization of the cervical spine in stationary and mobile traction following:

- Cervical fractures
- Ligamentous injury of the cervical spine
- Fusion or other surgery of the cervical spine

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Concurrence of CDRH, Office of Device Evaluation

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K974245

Prescription Use X  
(Per 21 CFR 801.109)

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