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February 3, 2004

510(k) Summary
As required by section 807.92(c)

Trade Name: Ceramic Tipped Skull Pins

Common Name: Traction Skull Pins

Classification Name: Single/multiple component metallic bone fixation appliances and accessories Sec. 888.3030 Class II LXT

Substantially Equivalent to: Jerome Traction Skull Pins (included in K822780 and K930153) also manufactured by Jerome Medical. Also similar to Traction Skull Pins included in Bremer Halo System Cervical Traction Skull Pin (K915800, K810193), DePuy Ace Skull Pin and Tong Pin (K974245) Friddle Halo System (K980689), and PMT Halo Systems. Copies of representative product literature are included in Competition (Tab 10).

Description: The Ceramic Tipped Skull Pins are similar to other skull pins which, when used as part of a Halo Traction System, are designed to hold the skull firmly in place relative to the torso so cervical vertebrae are immobilized following surgery or injury. They are the only invasive components of the Systems. The new Skull Pins include a ceramic tip. The ceramic tip reduces the possibility of an electric current passing to the patient. Such current may cause imaging artifact and/or a burning sensation at the pin insertion points. Engineering drawings of Ceramic Tipped Skull Pin assemblies are included in Device Name & Description, Tab 2.

Technological Characteristics Summary:

Table 2

	Ceramic Tipped Skull Pin	**Titanium Skull Pin**
Design	Threaded Skull Pin	Threaded Skull Pin
Materials	Ti6Al4V Titanium, ZrO-ATP BIO-HIP Ceramic, Epoxy	Ti6Al4V Titanium
Sterility	EtO Sterilized	EtO Sterilized
Sizes	1 size	2 sizes
Electrical Safety	Non-conductive	Conductive
Imaging Compatibility	Compatible w/X-ray, CT, MR	Compatible w/X-ray, CT, MR
Performance	Meets requirements of ASTM F 1831 – 97 for Mechanical Integrity of Halo Rings.	Meets requirements of ASTM F 1831 – 97 for Mechanical Integrity of Halo Rings.

JEROME

Jerome Medical, 305 Harper Drive, Moorestown, NJ 08057-3239 • (800) 257-8440 • FAX (856) 778-5333

The Ceramic Tipped Skull Pins are substantially equivalent to the Titanium Skull Pins. Differences are the use of non-conductive materials for improved image quality and patient safety; and thicker material (Halo Skull Pin: 0.3125 inch major diameter Ceramic Tipped Skull Pin vs. 0.250 inch Titanium Skull Pin) for offset load strength. Both clinical and laboratory tests confirm that the new material and design meet the same standard for mechanical integrity as the predicate device.

Laboratory Tests: Both the Ceramic Tipped Skull Pins and Generation 80 (Titanium) Skull Pins were tested to the standard of ASTM F 1831-97, section 11. Both met the standard. A test summary is at page 5-1. The material and design changes do not adversely affect product performance.

Intended Use: The Ceramic Tipped Skull Pins are intended for use in conjunction with the Jerome Halo System that provides cervical immobilization and/or traction for healing and rehabilitation of cervical spinal cord injuries.

Conclusions: The Ceramic Tipped Skull Pins are similar to previously approved Skull Pins in function and indications for use. The devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2004

Mr. Ronald S. Kowalski
President
Jerome Medical
305 Harper Drive
Moorestown, New Jersey 08057

Re: K040363
Trade/Device Name: Ceramic Tipped Skull Pin
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LYT
Dated: February 12, 2004
Received: February 18, 2004

Dear Mr. Kowalski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

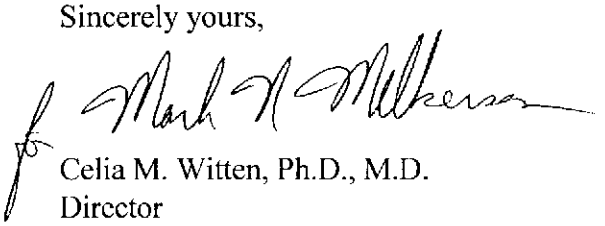
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040363

Device Name: Ceramic Tipped Skull Pin

Indications For Use: The Ceramic Tipped Skull Pins are similar to other skull pins which, when used as part of a Halo Traction System, are designed to hold the skull firmly in place relative to the torso so cervical vertebrae are immobilized following surgery or injury.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040363