DEC 15 1999

K993099

510(k) Summary

SUBMITTER:

DePuy AcroMed
325 Paramount Drive
Raynham, MA 02767
Fax (508) 828-3797

Bremer Medical
4801 Dawin Road
Jacksonville,FL 32207

CONTACT PERSON:

Frank Maas (508) 828-3390
Lisa Gilman (508) 880-8287

DATE PREPARED: 12-8-99

CLASSIFICATION NAME AND REFERENCE:

Smooth or threaded metallic bone fastener, §888.3040
Skull tong for traction, §888.3070

COMMON NAME: Traction Skull Pin

PROPRIETARY NAME: Bremer Halo System Titanium Skull Pin

PURPOSE: Modification of an existing device.

DESCRIPTION:

The Bremer Halo System Titanium Skull Pin described in this submission is a modification of the previously cleared Bremer Halo System Sterile Cervical Traction Skull Pin. The modified pin is longer than the previously cleared pin and the tip is a drill bit rather than a pointed tip.

The Bremer Halo System Titanium Skull Pin is manufactured from implant grade titanium alloy that conforms to ASTM standard F-136.

Testing was presented to evaluate the performance characteristics of the Bremer Halo System Titanium Skull Pin.

The substantial equivalence of the Bremer Halo System Titanium Skull Pin is based on an equivalence in intended use, materials, design, and relative indications and contraindications to the existing Bremer Halo System Sterile Cervical Traction Skull Pin.

The Bremer Halo System Titanium Skull Pin is intended for use in conjunction with Bremer's Halo System cervical traction devices and accessories (Halo System), which provide cervical immobilization necessary for healing and rehabilitation of cervical spinal cord injuries.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 1999

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K993099
Trade Name: Bremer Halo System Titanium Skull Pin
Regulatory Class: II
Product Code: JEC and HWC
Dated: September 13, 1999
Received: September 16, 1999

Dear Mr. Maas:

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 (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. 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R. P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993099

Device Name:

Indications for Use:

The Bremer Halo System Titanium Skull Pins are intended for use in conjunction with Bremer's Halo System cervical traction devices and accessories, which provide cervical immobilization necessary for healing and rehabilitation of cervical spinal cord injuries.

NRD for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993099

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CRF 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)