K023959
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November 22, 2002

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

Trade Name: Jerome Glass Ring

FEB 2 1 2003

Common Name: Halo Ring

Classification Name: Tong, Skull for Traction, Sec. 882.5960, Neurological Devices, Class II, HAX

Substantially Equivalent to: Generation 80 Halo Ring (K822780) also manufactured by Jerome Medical. Also similar to Halo Rings included in Lerman Low Profile Halo System, Bremer Halo System (K864746), (now DePuy Acromed – Johnson & Johnson), Friddle Halo System (K980689), PMT Halo Systems, and the V1 Halo Ring (K930153). Copies of product literature for each are included in Competition (Tab 10).

Description: The Fiberglass Halo Traction Ring is similar to other halo rings which, when used as part of a Halo System, are designed to hold the skull firmly in place relative to the torso so cervical vertebrae are immobilized following surgery or injury. An engineering drawing of a Standard size Glass Ring is at page 2-2.

Technological Characteristics Summary:

Table 2

	Jerome Glass Ring	**Generation 80**
Design	Closed Loop Halo Ring	Closed Loop Halo Ring
Materials	E-glass (fiberglass)	6061 T6 Aluminum
Sterility	EtO Sterilized	EtO Sterilized
Sizes	3 sizes	3 sizes
Pin Sites	31	19
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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

Mr. Bernie Tatro
Director of Marketing
Jerome Medical
305 Harper Drive
Moorestown, New Jersey 08057-3239

Re: K023959
Trade Name: Jerome Glass Ring
Regulation Number: 21 CFR 882.5960
Regulation Name: Skull tongs for traction
Regulatory Class: II
Product Code: HAX
Dated: November 25, 2002
Received: November 27, 2002

Dear Mr. Tatro:

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,

Miriam C. Provost

for 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

510(k) Number (if known): K023959

Device Name: Jerome Glass Ring

Indications for Use:

The Jerome Glass Ring is intended for use with a Jerome Halo Vest to immobilize and/or provide traction for a cervical spine injury.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023959