JEROME
CERVICAL SPINE SYSTEM
Helping You Meet The Challenge

AUG 17 2005

K051918

July 14, 2005

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

Trade Name: ReSOLVE Open Back Halo Ring

Common Name: Halo Ring

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

Substantially Equivalent To: ReSOLVE Closed Back Halo Ring (K023959) manufactured by Jerome Medical. Also similar to the V1 Halo Ring (K930153) manufactured by Jerome Medical.

Description: The ReSOLVE Open Back Halo Traction Ring is similar to other 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.

Technological Characteristics Summary:

	ReSOLVE Open Back Ring	**ReSOLVE Closed Back Ring**
Design	Open back halo ring	Closed loop halo ring
Materials	E-glass (glass composite)	E-glass (glass composite)
Sterility	EtO Sterilized	EtO Sterilized
Electrical Safety	Nonconductive	Nonconductive
Imaging Compatibility	Compatible w/X-ray, CT, MR	Compatible w/X-ray, CT, MR
Performance	Meets or exceeds requirements of ASTM F 1831-97 for Mechanical Integrity of Halo Rings	Meets or exceeds requirements of ASTM F 1831-97 for Mechanical Integrity of Halo Rings

The ReSOLVE Open Back Ring is substantially equivalent to the ReSOLVE Closed Back Ring in all technological aspects. The only variation is the shape of the ring. Laboratory tests confirm that the new open back design meets the same standard for mechanical integrity as the previously approved ReSOLVE Closed Back Ring.

Non-clinical Tests: Both the ReSOLVE Open Back and ReSOLVE Closed Back were tested to the standard of ASTM F 1831-97, Section 11. Each met the standard. The design change does not adversely affect product performance.

Intended Use: The ReSOLVE Open Back Halo Ring is intended for use in conjunction with the Jerome Halo Vest, Superstructure and Accessories (Halo System) that provide cervical immobilization and/or traction for healing and rehabilitation of cervical spinal cord injuries.

Conclusions: The ReSOLVE Open Back Halo Ring is similar to the ReSOLVE Closed Back Halo Ring in material, 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

AUG 17 2005

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

Re: K051918
Trade/Device Name: ReSOLVE Open Back Halo Ring
Regulation Number: 21 CFR 882.5960
Regulation Name: Skull tongs for traction
Regulatory Class: II
Product Code: HAX
Dated: July 14, 2005
Received: July 19, 2005

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.

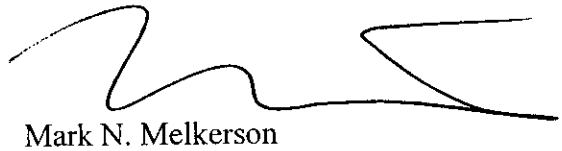
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting 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): K051918

Device Name: ReSOLVE Open Back Halo Ring

Indications for Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051918