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ÖSSUR

Life Without Limitations

April 24, 2007

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

Trade Name: ReSolve Tongs Traction Tongs

Common Name: Traction Tongs

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

Substantially Equivalent To: JTongs Traction Tongs (K930021) manufactured by Jerome Medical*. Also similar to the ReSolve Open Back Halo Ring (K051918) manufactured by Jerome Medical*.

Description: The ReSolve Tongs are similar to other traction tongs which are used to provide longitudinal traction to align vertebral structures, maintain reduction, or provide stabilization for a cervical spine injury.

Technological Characteristics Summary:

	ReSolve Tongs	**JTongs**
Design	Open tong	Open tong
Materials	E-glass (fiberglass)	Carbon composite
Sterility	EtO Sterilized	EtO Sterilized
Electrical Safety	Nonconductive	Conductive
Imaging Compatibility	Compatible w/X-ray, CT, MR	Compatible w/X-ray, CT
Performance	Meets requirements of ASTM F 1831-97 for Mechanical Integrity of Cranial Traction Tongs	Meets requirements of ASTM F 1831-97 for Mechanical Integrity of Cranial Traction Tongs

The ReSolve Tongs are substantially equivalent to the predicate JTongs in all technological aspects except electrical safety. Laboratory tests confirm that the new nonconductive design meets the same standard for mechanical integrity as the previously approved JTongs.

*Now Ossur Americas

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Non-clinical tests: The ReSolve Tongs were tested to the standard of ASTM F 1831-97, Section 10. They met the standard. The design change does not adversely affect product performance.

Intended Use: The ReSolve Tongs are intended for use to provide longitudinal traction to align vertebral structures, maintain reduction, or provide stabilization for a cervical spine injury.

Conclusions: The ReSolve Tongs are similar to the predicate device JTongs 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

Ossur Americas, Orthopaedics
c/o Mr. Bernie Tatro
Director of Distribution
1414 Metropolitan Avenue
Paulsboro, New Jersey 08066

MAY 25 2007

Re: K071173
Trade/Device Name: ReSolve Tongs Traction Tongs
Regulation Number: 21 CFR 882.5960
Regulation Name: Skull Tongs for Traction
Regulatory Class: II
Product Code: HAX
Dated: April 26, 2007
Received: April 27, 2007

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): _____

Device Name: ____ReSolve Tongs Traction Tongs_____

Indications for Use:

The ReSolve Tongs are intended for use to provide longitudinal traction to align vertebral structures, maintain reduction, or provide stabilization for a cervical spine injury.

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

510(k) Number K071173

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)