K030500
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510(k) SUMMARY

MAR 2 0 2003

Sponsor:	Eurosurgical, SA B.P.23-18 rue Robespierre Beaurains, France 62217 Phone: 33-3-2121 5960, Fax: 33-3-2121 5970
Contact Person:	Emmanuel Margerit, Regulatory Affairs and Quality Manager
Proprietary Trade Name:	ORIA ZENITH
Device Description:	The ORIA ZENITH is a cervical plate system consisting of plates and screws manufactured from titanium alloy (ASTM F 136). Plates are available in a variety of lengths. Fixed and variable screws are available in a variety of lengths and diameters of 4.0 and 4.5mm. A self-tapping version of each screw is also available.
Intended Use:	The ORIA ZENITH is intended for anterior screw fixation of the cervical spine and is designed to provide stabilization as an adjunct to spinal fusion at these levels. Indications for the use of this device include failed previous fusion, pseudarthrosis, tumor, deformity, spinal stenosis, trauma, spondylolisthesis or degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. WARNING: The ORIA ZENITH is <u>not</u> intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Materials:	The ORIA ZENITH is manufactured from titanium alloy (ASTM F136).
Substantial Equivalence:	Documentation was provided which demonstrated the ORIA ZENITH to be substantially equivalent to a previously cleared device. The substantial equivalence is based upon equivalence in indications/intended use, manufacturing methods, attachment mechanism, basic design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Eurosurgical, SA
c/o Ms. Karen E. Warden, MEBE
VP Regulatory Affairs & Research
REO Spine Line
7000 Hampton Center, Suite G1
Morgantown, West Virginia 26505

Re: K030500
Trade Name: ORIA ZENITH
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 18, 2003
Received: February 19, 2003

Dear Ms. Warden:

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,

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

Indications for Use Statement

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Device Name: **ORIA ZENITH**

Indications for Use:

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for Mark N Melkerson

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

510(k) Number K030500

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)