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NOV 2 0 2003

510(k) SUMMARY

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 Spinal Clip System
Device Description:	The ORIA Spinal Clip System includes components that fit together to form a construct for use during spinal fusion surgery. The system contains components of various designs and sizes that allow the surgeon to build an implant system for each of four defined indications and to fit the patient's anatomical and physiological requirements. The components include: lumbar, thoracic, and pedicular hooks; sacral screws; pedicle screws; set screws; locking nuts; rods in various lengths; connectors with set screws (sacral, transverse, lateral); connecting elements; instruments and sterilizer trays.
Intended Use:	When used as a nonpedicle, noncervical posterior system, the ORIA Spinal Clip System is indicated for: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); (2) spondylolisthesis; (3) fracture; (4) spinal stenosis; (5) deformities (i.e., scoliosis, kyphosis, lordosis), (5) tumor, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion. ORIA Spinal Clip System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) at L5-S1 joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of solid fusion mass. When used as a pedicle screw system in the non-cervical spine of skeletally mature patients, the ORIA Spinal Clip System is indicated for immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative spondylolisthesis with objective evidence of neurological impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and (7) failed previous fusion (pseudarthrosis).
Materials:	The ORIA Spinal Clip System Domino Connectors are manufactured from titanium alloy (ASTM F136) and stainless steel ASTM (F138).
Substantial Equivalence:	Documentation was provided which demonstrated the ORIA Spinal Clip System Domino and Tube Connectors to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, anatomic sites, design, material of manufacture, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

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

Re: K030958
Trade/Device Name: ORIA Spinal Clip System
Regulatory Number: 21 CFR 888.3070, 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: August 28, 2003
Received: September 2, 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) 594-4639. 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

Indications for Use Statement

510(k) Number (if known): K030958

Device Name: **ORIA Spinal Clip System**

Indications for Use:

When used as a nonpedicle, noncervical posterior system, the ORIA Spinal Clip System is indicated for: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); (2) spondylolisthesis; (3) fracture; (4) spinal stenosis; (5) deformities (i.e., scoliosis, kyphosis, lordosis), (5) tumor, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

ORIA Spinal Clip System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) at L5-S1 joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of solid fusion mass.

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Miriam C. Provost

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

510(k) Number K030958

(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)