K021679

page 1 of 4

Summary of Safety and Effectiveness Information	EUROSURGICAL, S.A.
Premarket Notification, Section 510(k)	OCTOBER 24, 2002

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

ORIA SPINAL CLIP SYSTEM

NOV 1 9 2002

Common Name(s):

Pedicle screw spine system

Classification Name(s):

Pedicle Screw Spinal System
Spinal Interlaminal Fixation Orthosis
Spondylolisthesis Spinal Fixation Device System

2. Establishment Information:

Name: Eurosurgical, S.A.

Number: 9032545

Address: BP 23-18, rue Robespierre
Beaurains, FRANCE 62217
33 3 21 21 59 60 – voice
33 3 21 21 59 70 – fax
www.eurosurgical.com

3. Classification(s):

§ 888.3050 – Spinal Interlaminal Fixation Orthosis
§ 888.3070 – Pedicle Screw Spinal System

Class II (special controls) apply to all such systems. Pedicle screw spinal systems must comply with the following special controls:

(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatability standard, and
(iv) Labeling which contains the following statements in addition to other appropriate labeling information.

"**Warning:** The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

"**Precaution:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."

(b) Pedicle screw spinal systems for all other uses (1) Identification. Pedicle screw spinal systems for all other uses are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(2) Classification. Class III (premarket approval)

(c) Date PMA or notice of completion of a PDP is required. An approved PMA or a declared completed PDP must be in effect before placing the device in commercial distribution. See Sec. 888.3.

Device Class: Class II for the requested indications

Classification Panel: Orthopaedic and Rehabilitation Devices Panel

Product Code(s): KWP, MNH and MNI respectively

4. Equivalent Predicate Device:

The ORIA ***Spinal Clip System*** is substantially equivalent to several legally marketed spinal device systems. The system has been evaluated and found to be substantially equivalent to devices marketed in the following categories:

§ 888.3050 – Spinal Interlaminal Fixation Orthosis
§ 888.3070 – Spondylolisthesis Spinal Fixation Device System
§ 888.3070 – Pedicle Screw Spinal System (Class II Uses)

The comparison devices use various rods, screws, crosslinks, couplers, bushings, inserts and other components intended for use in the treatment of spinal instability or deformity. Equivalency can be seen with respect to the design, material composition, labeling, indications for use, cautions, precautions and warnings.

5. Device Description:

System Components Include:
Hooks
Nuts
Clips
Rods
Crosslinks
Pedicle Screws
Sacral Screws
Unique Instrumentation

Materials: Certified implant grades of commercially pure titanium, titanium alloy and stainless steel are used to make the implants of the system.

Intended Use – 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) pseudoarthrosis, (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).

Testing Summary: Static and fatigue testing were conducted. Static tests of compression bending, tension bending and torsion of a typical system configuration indicated design performance was met. All samples were fatigue tested according to a modified Cunningham model. Samples subjected to cyclic fatigue testing also performed according to expectations. Constructs were tested and an S/N curve established. At least two run out points exceeded 5,000,000 load cycles at clinically useful loads.

6. ***Company Contact:***

Mr. Emmanuel Margerit
Eurosurgical, S.A.
BP 23-18, rue Robespierre
Beaurains, FRANCE 62217
33 3 21 21 59 60 – voice
33 3 21 21 59 70 – fax
www.eurosurgical.com

7. ***Submission Correspondent:***

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

8. ***Performance Standards:***

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9001 series quality regulations.

Eurosurgical, S.A. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

9. Special Controls:

Special controls were published in the Federal Register, Vol. 63, No. 143, July 27, 1998 (Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems). The following special controls apply to the marketing of this device when used as a posterior pedicle system:

(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatability standard, and
(iv) Compliance with specified labeling requirements.

10. Sterilization Information:

The ORIA ***Spinal Clip System*** is supplied ***"NON-STERILE"*** and must be sterilized prior to use. The recommended sterilization process is high temperature steam autoclave sterilization. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:

Method:	Steam
Cycle:	Gravity
Temperature:	250°F (121°C)
Exposure Time:	30 minutes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

Eurosurgical S.A.
c/o Mr. David W. Schlerf
Regulatory Consultant
Buckman Company
200 Gregory Lane Suite C-100
Pleasant Hill, California 94529

Re: K021679
Trade Name: ORIA Spinal Clip System
Regulation Numbers: 888.3050 and 888.3070
Regulation Names: Spinal Interlaminal Fixation Orthosis; Pedicle Screw Spinal System; and Spondylolisthesis Spinal Fixation Device System
Regulatory Class: II
Product Codes: KWP; MNI; and MNH
Dated: September 8, 2002
Received: September 30, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, 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). Other general information on your responsibilities under the Act may be obtained 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 Mark N Melkerson

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 : ~~K021697~~ K021679

Device Name(s): ***ORIA Spinal Clip System***

Intended Use(s) of the Device:

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) pseudoarthrosis, (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).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K021679

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96