MAY - 3 2004

K040514

Attachment VIII 510k 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:	EOVIA® Calcium Phosphate Ceramic
Device Description:	EOVIA is a synthetic, resorbable calcium phosphate bone void filler. It is an osteoconductive material, which provides a porous scaffold upon which bone formation can occur. The interconnected porosity ranges from 60 to 80% with a pore size range between 200-500µm. EOVIA is available in granule or rods shapes.
Intended Use:	EOVIA Calcium Phosphate Ceramic is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. EOVIA Calcium Phosphate Ceramic is to be gently packed into bony voids or gaps of the skeletal system (e.g., the spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. EOVIA Calcium Phosphate Ceramic provides a bone void filler that is resorbed and is replaced with bone during the healing process.
Materials:	The EOVIA Calcium Phosphate Ceramic is manufactured from tricalcium phosphate (80%) and hydroxyapatite (20%) according to ASTM F1088 and 1185, respectively.
Substantial Equivalence:	Documentation was provided which demonstrated the EOVIA Calcium Phosphate Ceramic to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, anatomic sites, design, material and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2004

Eurosurgical, SA
C/o Karen E. Warden, MEBE
Representative/Consultant
REO Spine Line
7000 Hampton Center, Suite G-1
Morgantown, West Virginia 26505

Re: K040514
Trade/Device Name: EOVIA® Calcium Phosphate Ceramic
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: February 25, 2004
Received: February 27, 2004

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 Mark A. Milken

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment II Indications for Use Statement

510(k) Number (if known): K040514

Device Name: **EOVIA®** Calcium Phosphate Ceramic

Indications for Use:

EOVIA Calcium Phosphate Ceramic is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. **EOVIA** Calcium Phosphate Ceramic is to be gently packed into bony voids or gaps of the skeletal system (e.g., the spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. **EOVIA** Calcium Phosphate Ceramic provides a bone void filler that is resorbed and is replaced with bone during the healing process.

Prescription Use _X_ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K040514