FEB 12 2004

Titanium Mesh
510(k) Summary of Safety and Effectiveness

K032371

SUBMITTER:	Encore Orthopedics, Inc. 9800 Metric Blvd Austin, TX 78758
CONTACT PERSON:	Kimberly L. Pruitt (512) 834-6291
PROPRIETARY NAME:	Titanium Mesh
COMMON NAME:	Titanium Mesh
CLASSIFICATION NAME:	Per CFR 21, §888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices
PRODUCT CLASSIFICATION:	Class II
DEVICE PRODUCT CODE:	MQP
PREDICATE DEVICE:	(K003275) SynMesh™ Spacer System (K003709) Surgical Dynamics™ Mesh Cage System (K003043) DePuy AcroMed™ Surgical Titanium Mesh™ System
DEVICE DESCRIPTION:	The Titanium Mesh is a vertebral body replacement system comprised of several different cross-sectional shaped implants with various heights. The different cross-sectional shaped shapes include: round, oval, oblong and kidney (banana) shaped implants. The height of the implants varies from 7mm to 130mm. In addition, some of the implants are trapezoidal, i.e., the posterior side of the implant is lower than the anterior side of the implant. A cutting tool allows for trimming of the implants to the desired height at surgical site. The interior of the mesh is open and provides a space that can be filled with bone graft material. The sidewalls of the mesh are perforated by several holes and allow for bone fusion through the sidewalls of the mesh. There are several ribs running longitudinally along the internal walls of the mesh. Standard and trapezoidal end caps that correspond to the various cross-sectional shapes of meshes are included in the system. The end caps are placed on

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top of and supported by the longitudinal ribs located at the internal wall of the mesh. Also the end caps have prongs that provide a friction-locking feature between the caps and the ribs of the mesh. The end caps are manually pressed into the mesh. Serrations on the superior/inferior surface of the end caps provide stability and prevent movement of the implant.

The Titanium Mesh System is intended for use with supplemental internal fixation spinal systems.

INTENDED USE:

The Titanium Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture), to achieve anterior decompression of the spinal cord and other neutral tissues, and to restore the height of a collapsed vertebral body. The Titanium Mesh is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Titanium Mesh System is similar in indications, material and design to the SynMesh™ Spacer System (K003275), the Surgical Dynamics™ Mesh Cage System (K003709) and the DePuy AcroMed™ Surgical Titanium Mesh™ System (K003043).

MATERIALS:

The Titanium Mesh System is manufactured from surgical grade titanium alloy as described by ASTM F-1108 (Ti-6Al-4V).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2004

Ms. Kimberly L. Pruitt
Clinical Research Associate
Encore Medical L.P.
9800 Metric Boulevard
Austin, Texas 78758

Re: K032371
Trade/Device Name: Titanium Mesh System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: January 23, 2004
Received: January 26, 2004

Dear Ms. Pruitt:

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.

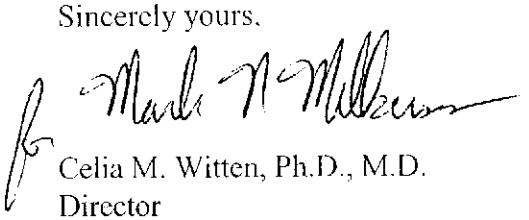
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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 (if known): K032371-S1

Device Name: Titanium Mesh System

Indications For Use:

Titanium Mesh System
Indications For Use

The Titanium Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture), to achieve anterior decompression of the spinal cord and other neutral tissues, and to restore the height of a collapsed vertebral body. The Titanium Mesh is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The-Counter Use ___ (Optional Format 1-2-96)

for Mark N Milhern

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

510(k) Number K032371