510(k) SUMMARY

SUBMITTED BY

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JAN 2 3 2003

July 1, 2002

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Vertebral Body Replacement
Common/Usual Name: Vertebral Body Replacement
Product Classification: Class II
Proprietary Name: Interpore Cross International Anterior Fixation Device (AFD)

PREDICATE DEVICE

The predicate device is the GEO™ Structure that is currently manufactured and distributed by Interpore Cross International.

INDICATIONS-FOR-USE

The Interpore Cross International AFD is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Interpore Cross International AFD is also indicated for treating fractures of the thoracic and lumbar spine. The Interpore Cross International AFD 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.

DEVICE DESCRIPTION

The Interpore Cross International AFD is a titanium alloy spacer for vertebral body replacement. It has a predominately hollow center and outer ring with screws for fixation into the vertebral bodies. The hollow center allows for the addition of bone graft material. In addition, there are ridges on the superior and inferior surfaces of the implant to enhance placement and prevent expulsion.

COMPARISON TO THE PREDICATE DEVICE

The Interpore Cross International AFD is substantially equivalent to the GEO Structure that is currently manufactured and distributed by Interpore Cross International. Both implants are used to treat the same conditions, have essentially the same precautions and contraindications for use, and have equivalent potential for complications for the risk of use. In addition, they both represent a basic design concept in terms of safety and effectiveness, and differ only in minor details. Based on the basic design concept, the use of established well known materials, feature comparisons, mechanical testing, indications for use, preproduction quality assurance planning and engineering analysis, Interpore Cross International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to the existing legally marketed device.

DISCUSSION OF NONCLINICAL TESTS

Data regarding the functional performance of the proposed Interpore Cross International AFD has been generated. Mechanical testing, including static axial compression, torsional loading, shear compression and expulsion testing indicates that the proposed Interpore Cross International AFD meets or exceeds all functional requirements and supports its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

Ms. Wendy Spielberger
Senior Clinical Regulatory Coordinator
Interpore Cross International
181 Technology Drive
Irvine, CA 92618-2402

Re: K022143
Trade/Device Name: Interpore Cross International Anterior Fixation Device
Regulation Number: 21 CFR 888.3060
Regulation Name: Vertebral body replacement device
Regulatory Class: Class II
Product Code: MQP
Dated: November 20, 2002
Received: November 21, 2002

Dear Ms. Spielberger:

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" (21 CFR Part 807.97) you may obtain. 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 (if known): K022143

Device Name: Interpore Cross International Anterior Fixation Device (AFD)

Indications-For-Use:

The Interpore Cross International AFD is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Interpore Cross International AFD is also indicated for treating fractures of the thoracic and lumbar spine. The Interpore Cross International AFD 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)

for Mark N Melkerson

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

510(k) Number K022143

Prescription Use _____ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)