MAY 1 6 2002

K020887

510(k) Summary

This 510(k) Summary for the EBI AIS System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Jon Caparotta, RAC
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Date prepared: May 1, 2002

2. **Proprietary Name:** EBI AIS Spine System
Common Name: Spinal Fixation Device
Classification Name/Code: Spinal Vertebral Body Replacement Device/MQP

3. **Predicate or legally marketed devices that are substantially equivalent:**

- Rezaian Spinal Fixator by OEM (K841189)
- Stackable Cage™ System by Depuy Acromed (K990148, K001340)
- SynMesh™ System by Synthes (K003275)
- Geo™ Structure by Interpore Cross (K010530)

4. **Description of the device:** The EBI AIS Spine System is a vertebral body replacement device comprised of an anatomically shaped titanium implant. The EBI AIS is a single component device with a solid center core that provides structural integrity and slotted platforms that allows for bone growth around the center core. The superior and inferior platforms are flared outward to allow greater surface contact. The platforms are also designed with fins, which grip into the endplates of the vertebral body to reduce implant migration.

5. **Intended Use:** The EBI AIS Spine System is intended for use in the thoracolumbar spine (i.e., T1 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 EBI AIS Spine System is also indicated for treating fractures of the thoracic and lumbar spine. The EBI AIS Spine System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged time. The system must be used in conjunction with the EBI Omega21 System or the EBI SpineLink System.

6. **Materials:** The AIS Spine System is manufactured from Titanium, Ti-6Al-4V ELI, per ASTM F136.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the AIS Spine System and other currently marketed spine systems. The AIS Spine System is substantially equivalent* to the predicate devices in regards to intended use, materials and function. Mechanical testing comparing the AIS System to a predicate system demonstrated that the device complies with applicable standards and guidelines and meets all of its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2002

Mr. Frederic Testa, RAC
Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K020887
Trade/Device Name: EBI AIS Spine System
Regulation Number: 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: March 15, 2002
Received: March 18, 2002

Dear Mr. Testa:

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 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,

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

510(k) Number (if known): K020887

Device Name: **EBI AIS Spine System**

Indications For Use:

The EBI AIS Spine System is intended for use in the thoracolumbar spine (i.e., T1 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 EBI AIS Spine System is also indicated for treating fractures of the thoracic and lumbar spine. The EBI AIS Spine System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged time. The system must be used in conjunction with the EBI Omega 21 System or the EBI SpineLink System.

(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)

Miriam C. Provost

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

510(k) Number K020887