K071663
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510(k) Summary according to 807.92(c)

JUL - 2 2008

Contact: Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
(202) 552 – 5800

Trade Name: Orthobiom™ Spinal System

Common Name: Pedicle Screw System

Device Regulatory Class: Pedicle Screw System (21 CFR 888.3070)
Class II

Product Code: 87MNI

Indications For Use:
The Orthobiom™ Spinal System is a posterior, non-cervical pedicle screw system indicated to treat pediatric scoliosis by (1) correction, (2) stabilization, (3) adjustment and (4) fixation of the scoliotic spine.

The Orthobiom™ Spinal System is intended to be used with bone graft.

Device Description:
The Orthobiom™ Spinal System is designed as a pedicle screw based system. The system consists of rods, pedicle screws, fixed connectors, and one cross connector. The Orthobiom™ Spinal System uses rods, screws, and/or hooks to achieve correction and subsequent maintenance of the corrected scoliotic spine and use fusion to maintain the corrected spine.

Predicate Device(s):
The Orthobiom Spinal System™ was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These predicates include Harrington Rods (K781443), Synthes Small Stature USS (K994121), DePuy Spine Kaneda Spinal System (K974757), Acromed Pediatric ISOLA (K962984), and DePuy Spine Frontier Anterior Deformity System (K012916).

Performance Standards:
Testing performed indicate that the Orthobiom™ Spinal System is as mechanically sound as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Musculoskeletal Clinical Regulatory Adviser, LLC
% Mr. Justin Eggleton
1131 H Street NW
12th Floor
Washington, DC 20005

JUL - 2 2008

Re: K071668
Trade/Device Name: Orthobiom™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI
Dated: April 2, 2008
Received: April 3, 2008

Dear Mr. Eggleton:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071668

Device Name: Orthobiom™ Spinal System

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Prescription Use __√__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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 K071668