K090376

SpineSmith Cynch Spinal System

APR - 1 2009

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	SpineSmith Partners, LP 8140 N. Mopac, Bldg II, Suite 120 Austin, TX 78759
ESTABLISHMENT REGISTRATION NUMBER	3006404071
CONTACT PERSON	Robert Jones Vice President, Research and Development Phone: 512-206-0770 Fax: 512-637-6750 Email: rjones@spinesmithusa.com
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746
DATE PREPARED	February 16, 2009
CLASSIFICATION	MAX 888.3080- Intervertebral Fusion Device with Bone Graft, Lumbar
COMMON NAME	Intervertebral Body Fusion Device
PROPRIETARY NAME	SpineSmith Cynch Spinal System
SUBSTANTIAL EQUIVALENCE	The SpineSmith Cynch System was determined to be substantially equivalent to several recently down classified cages: - LT-CAGE® Peek Lumbar Tapered Fusion Device (P970015, Medtronic Sofamor Danek, Approved 9/10/03) - BAK® Cage (P950002, Zimmer Spine, Approved 7/8/03) - RAY® Threaded Fusion Cage (P950019, Stryker, Approved 9/4/03) - Lumbar I/F Cage (P960025, DePuy, Approved 3/4/05)

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DEVICE DESCRIPTION

Cynch is curved to allow for medial-lateral placement of the device, and is available in two footprints (25mm and 30mm) with a 5° lordosis in various heights. Cynch is hollow to allow for the placement of autograft bone, and has large anterior graft windows to facilitate fusion. There are teeth on the superior and inferior surface of the device to provide increased stability and inhibit movement of the implant.

INDICATIONS:

The Cynch System is indicated intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

MECHANICAL TEST DATA

Mechanical test results demonstrate that the Cynch System is substantially equivalent to the predicate.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SpineSmith Partners, LP
% Mr. Robert Jones
Vice President, Research and Development
8140 N. Mopac, Building II, Suite 120
Austin, Texas 78759

APR - 1 2009

Re: K090376
Trade/Device Name: SpineSmith Cynch Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: February 16, 2009
Received: February 17, 2009

Dear Mr. Jones:

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.

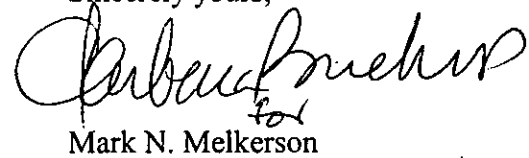
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K090376

Device Name: **SpineSmith Cynch Spinal System**

Indications for Use:

The Cynch System is indicated intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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

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