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4. 510(k) Summary according to 807.92(c)

Contact: Tim Lusby
Spinal Devices™, LLC
1155 Allgood Road, Suite 6
Marietta, GA 30062
770-874-0935

JAN 13 2009

Trade Name: Phenix ® Cervical Interbody Device (Phenix ® CID)
Product Class: Class II
Classification: 888.3080
Product Codes: ODP
Panel Code: 87

Indications for Use: The Phenix Cervical Interbody Device (Phenix CID) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Phenix CID implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

Device Description: The Phenix ® Cervical Interbody Device is a cervical interbody fusion device made from PEEK Optima. It is implanted from the anterior approach. The device is provided in various geometries and is designed to fit within the outer cortex of cervical spine vertebrae. It is to be packed with autogenous bone graft to facilitate fusion. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

Predicate Device(s): The predicate devices previously cleared by FDA are the BAC/Cervical Implant from Zimmer Spine (previously approved as a PMA product under the name of Spine-Tech) (P980048), and the Medicrea IMPIX Interbody Device (K072226).

Performance Testing: The pre-clinical testing performed indicated that the Phenix CID is substantially equivalent to the predicate devices and is adequate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2009

Spinal Devices™, LLC
% Mr. Tim Lusby
1155 Allgood Road, Suite 6
Marietta, Georgia 30062

Re: K083167
Trade/Device Name: Phenix® Cervical Interbody Device (Phenix® CID)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: December 12, 2008
Received: December 16, 2008

Dear Mr. Lusby:

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

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3. Statement of Indications for Use

510(k) Number: 083167

Indications for Use: The Phenix Cervical Interbody Device (Phenix CID) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Phenix CID implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

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 OF NEEDED)

Mark N Milkerson

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

510(k) Number K083167

Concurrence of CDRH, Office of Device Evaluation (ODE)