K073320

510(k) Summary

Date Submitted:	November 21, 2007
Manufacturer:	SpineSmith USA 5300 N. Lamar, Suite 107 Austin, TX 78751
Contact Name:	Robert Jones
Phone:	512-302-0086
Device Trade Name:	Cimplicity
Common Name:	Interbody Fusion Device
Regulatory Class:	888.3080
Classification Code:	Class II
Product Code:	ODP
Predicate Devices:	Affinity Cervical Cage (P000028) and others.
Device Description:	The Cimplicity system is a rectangular interbody fusion device. The device is hollow and may be filled with graft material. Various sizes are provided to accommodate patient anatomy.
Intended Use:	The Cimplicity Spinal Fixation System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Cimplicity implants are to be used with autogenous bone graft and implanted via an open, anterior approach.
Materials:	Cimplicity is made from PEEK and has tantalum beads used for radiographic visualization.
Substantial Equivalence:	The Cimplicity Spinal System was tested and compared to predicate devices and found to be substantially equivalent in terms of intended use, mechanical properties and material composition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2008

Spine Smith Partners L.P.
% Mr. Robert Jones
Vice President, Research and Development
5300 North Lamar Boulevard #107
Austin, Texas 78751

Re: K073320
Trade/Device Name: Cimplicity Spinal Fixation System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 11, 2008
Received: January 14, 2008

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Statement of Indications for Use

510(k) Number: K073320

Device Name: Cimplicity Spinal Fixation System

Indications for Use:

The Cimplicity Spinal Fixation System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Cimplicity implants are to be used with autogenous bone graft and implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use_X_____ OR Over the counter_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Buchman

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

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