

**SpineSmith Cequence Anterior Cervical Plate System**  
**510(k) Summary of Safety and Effectiveness**

**JUL 14 2008**

**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  
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**SUBMISSION PREPARED BY** Lisa Peterson  
Kaedon Consulting, LLC  
Phone: 512-507-0746

**DATE PREPARED** April 18, 2008

**CLASSIFICATION** KWQ 888.3060- Spinal Intervertebral Body Fixation  
Orthosis

**COMMON NAME** Spinal Fixation System

**PROPRIETARY NAME** SpineSmith Cequence Anterior Cervical Plate System

**SUBSTANTIAL  
EQUIVALENCE** The SpineSmith Cequence System was determined to be  
substantially equivalent to the predicate device.

**DEVICE DESCRIPTION**

The Cequence anterior cervical plates are preassembled and are offered in both a constrained and semi-constrained configuration. Cequence consists of four (4) primary components: 1) anterior plate, 2) self-tapping bone screws, 3) locking screws and 4) locking plate.

## **INDICATIONS:**

The SpineSmith Cequence Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine at one level between C2-C7 for the following indications:

- Degenerative disc disease [DDD] – defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spinal Stenosis
- Tumors
- Trauma (i.e. fracture)

## **MECHANICAL TEST DATA**

Mechanical test results demonstrate that the proposed Cequence System is substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Spine Smith Partners, L.P.  
% Mr. Robert Jones  
8140 North Mopac  
Building II, Suite 120  
Austin, TX 78759

**JUL 14 2008**

Rc: K081132  
Trade/Device Name: SpineSmith Partners, LP Cequence Anterior  
Cervical Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Names: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: KWQ  
Dated: June 27, 2008  
Received: June 30, 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.

Page 2 – Mr. Robert Jones

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):

Device Name: SpineSmith Partners, LP **Cequence Anterior Cervical Plate System**

Indications for Use:

The SpineSmith Cequence Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine at one level between C2-C7 for the following indications:

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Prescription Use   X  

AND/OR

Over-The-Counter Use           

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number   K081132