**SpineSmith IN:C2 Spinal Fixation System**

**510(k) Summary of Safety and Effectiveness**

DEC 5 2012

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| **SUBMITTED BY** | SpineSmith Partners, LLP<br>93 Red River<br>Austin, TX 78701 |
| **ESTABLISHMENT REGISTRATION NUMBER** | 3006404071 |
| **CONTACT PERSON** | **Clifton (Chris) Naivar**<br>Director – Quality and Regulatory Affairs<br>Phone: 512-637-2068<br>Fax: 512-637-2096<br>Email: cnaivar@spinesmithusa.com |
| **SUBMISSION PREPARED BY** | **Clifton (Chris) Naivar**<br>Director – Quality and Regulatory Affairs<br>Phone: 512-637-2068 |
| **DATE PREPARED** | September 30, 2012 |
| **CLASSIFICATION** | OVE - intervertebral fusion device with integrated fixation, cervical |
| **REGULATION NUMBER** | 21 CFR 888.3080 |
| **COMMON NAME** | Intervertebral Body Fusion Device |
| **PROPRIETARY NAME** | SpineSmith IN:C2 Spinal Fixation System |

**IDENTIFICATION OF PREDICATE DEVICES:**
The SpineSmith IN:C2 System was determined to be substantially equivalent to the previously cleared Cimplicity System (K080971) as well as the Coalition Spacer (K083389) and the InterPlate C-Ti (K092070).

**DEVICE DESCRIPTION:**
SpineSmith Partners LLP developed the IN:C2 Spinal Fixation System to be used during spinal fusion. IN:C2 serves to stabilize the spine while bony fusion develops.

The IN:C2 System consists of a 'U' shaped PEEK block in multiple footprint configurations, heights and lordosis angles. The PEEK implants contain a titanium marker intended to verify position radiologically. The IN:C2 is a stand-alone system, intended for use with its cover plate assembly and two titanium bone screws provided. The IN:C2 implant is intended to be implanted via an open anterior approach.

The anterior cover plate assembly attaches to the anterior most portion of the device, and includes housing features for placement of two bone screws angled cephalad and caudal. The cover plate assembly and integrated screws are supplemental fixation.

**INDICATIONS:**
The IN:C2 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. IN:C2 is a stand-alone device intended to be used with an anterior cover plate and a minimum two provided bone screws angled both cephalad and caudal with a minimum of one screw into each vertebral body. The 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.

**MECHANICAL TESTING:**
The following non-clinical tests were conducted:

- ASTM F2077-03, Test Methods for Intervertebral Body Fusion Devices.
- ASTM F2267-04, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression.
- Draft Document Submitted to ASTM F-04.25.02.02, Static Pushout Test Method for Intervertebral Body Fusion Devices.
- ASTM F1877–05 Standard Practice for Characterization of Particles

**CONCLUSIONS:**
The subject and predicate device share the same intended use, primary implant design and material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the IN:C2 System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 5, 2012

Spine Smith Partners, L.P.
% Clifton Naivar
Director, Quality and Regulatory Affairs
93 Red River
Austin, Texas 78701

Re: K122630
Trade/Device Name: IN:C2 Spinal Fixation System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: November 2, 2012
Received: November 5, 2012

Dear Mr. Naivar

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K122630**

Device Name: **IN:C2 Spinal Fixation System**

Indications for Use:

The IN:C2 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. IN:C2 is a stand-alone device intended to be used with an anterior cover plate and a minimum two provided bone screws angled both cephalad and caudal with a minimum of one screw into each vertebral body. The 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___ (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)

Caroline Rhim -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: 122630