SpineSmith Solum IV ® Bone Void Filler, Bone Graft Substitute

MAY 2 1 2014

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	SpineSmith Partners, LLP 93 Red River Austin, TX 78701
ESTABLISHMENT REGISTRATION NUMBER	3006404071
CONTACT PERSON	**Clifton (Chris) Naivar** Director – Quality and Regulatory Affairs Phone: 512-637-2068 Fax: 512-637-2096 Email: cnaivar@spinesmithusa.com
SUBMISSION PREPARED BY	**Clifton (Chris) Naivar** Director – Quality and Regulatory Affairs Phone: 512-637-2068
DATE PREPARED	May 14, 2014
CLASSIFICATION	Class II MQV - Resorbable calcium salt bone void filler device. 888.3045
COMMON NAME	Filler, bone void, calcium compound
PROPRIETARY NAME	Solum IV Bone Void Filler

IDENTIFICATION OF PREDICATE DEVICES:
Solum IV was determined to be substantially equivalent to the previously cleared nanOss BVF-E, K081558, Pioneer Surgical Technology, Cleared August 25, 2008. Solum IV is similar to nanOss BVF-E in characteristics which includes indication, ceramic materials, gelatin carrier, structure and presentation.

DEVICE DESCRIPTION:
Solum IV ® is a resorbable porous calcium phosphate bone void filler mixed with a porcine gelatin based carrier. It is an osteoconductive implant with a multidimensional porosity similar to human cancellous bone and acts as a scaffold for the in-growth of new bone.It is provided sterile in various configurations within a double sealed package containing a mixing spatula.

INDICATIONS:
Solum IV ® is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (i.e., extremities and pelvis) in conjunction with an equal volume of bone marrow

aspirate. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

TECHNOLOGICAL CHARACTERISTICS:
Solum IV ® is composed of porous hydroaxyapatite granules and a Type A porcine gelatin based carrier. The granules consist of macroporous ceramic granules composed of greater than 95% hydroxyapatite (HAp). The calcium phosphate granuals are presented as ground particles. The macroporous sturcture of Solum IV provides a resorbable osteoconductive scaffold.

The gelatin based carrier is presented as ground freeze-dried particles. The product forms a cohesive and adhesive dough with a putty-like consistency upon hydration which allows the shape of the implant to conform to the defect maximizing direct contact with viable host bone.

A summay of the technological characteristics comparing Solum IV to the predicate nanOss BVF-E (K081558) is listed in the table below.

Specification	Solum IV	Predicate nanOss
Device Material	Type A Gelatin and HAp	Type A Gelatin and HAp
Particle Size	.5mm-2.5mm	.5mm-2.5mm
Ca/P Ratio	1.66	1.66
Porosity (As determined by % Density)	80%	71%
Crystalline Structure	>95%	>95%

TESTING:
Solum IV and/or its components have undergone non-clinical testing including chemical, physical, animal, component biocompatibility, and handling characteristics. A critically sized defect implantation animal study demonstrated that Solum IV performed as well as the predicate device. Testing has provided a reasonable assurance of safety and effectiveness for its intended use with respect to the predicate device and supports a determination of substantial equivalence to the predicate device.

CONCLUSIONS:
The comparisons and testing conducted on Solum IV demonstrate that Solum IV and the predicated device nanOss BVF-E (K081558) have similar technological characteristics, intended use, and in vivo performance in a critically sized defect animal study, and therefore are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

SpineSmith Partners, LLP
Mr. Clifton (Chris) Naivar
Director, Quality and Regulatory Affairs
93 Red River Street
Austin, Texas 78701

Re: K132470
Trade/Device Name: Solum IV Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: April 14, 2014
Received: April 15, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

for
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): **K132470**

Device Name: **Solum IV Bone Void Filler**

Indications for Use:

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132470