



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Spine View, Incorporated
% Ms. Sevrina Ciucci
Regulatory Affairs Consultant
Lince Consulting
8 Crow Canyon Court, #205
San Ramon, California 94583

February 24, 2016

Re: K152539

Trade/Device Name: SpineView X-Pac Expandable Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 22, 2016
Received: January 27, 2016

Dear Ms. Ciucci:

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" (21 CFR 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,

Mark N. Melkerson -S

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)
K152539

Device Name
SpineView X-Pac Expandable Lumbar Cage System

Indications for Use (Describe)

The SpineView X-Pac Expandable Lumbar Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients. The system is designed for use with autogenous bone graft material to facilitate spinal fusion.

The system is intended for use in patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have at least 6 months of non-operative treatment prior to surgery. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via transforaminal approach using autogenous bone graft material. The system is intended for use with supplemental fixation systems cleared for use by the FDA for use in the thoracolumbar spine.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone, and Fax Number of Applicant

Spine View, Inc.
48810 Kato Road, Suite 100E
Fremont, CA 94538
Phone: (510) 743-5090
Fax: (510) 490-1753

B. Contact Person

Sevrina Ciucci
Regulatory Affairs Consultant

C. Date Prepared

August 31, 2015

D. Device Name and Classification

Trade Name:	SpineView X-Pac Expandable Lumbar Cage System
Common Name:	Intervertebral Body Fusion Device
CFR Classification:	21 CFR§888.3080
Classification Name:	Intervertebral Body Fusion Device
Product Code:	MAX

E. Predicate Device

The SpineView X-Pac Expandable Lumbar Cage System is substantially equivalent to the Globus Medical, Inc., Caliber Spacers, K123231.

F. Device Description

The SpineView X-Pac Expandable Lumbar Cage System is a lumbar interbody fusion system comprised of a cage implant and instruments. The implants are used to provide structural stability in skeletally mature individuals following discectomy and are placed via the transforaminal approach. The device is available in various sizes to accommodate varying anatomy and can expand to the desired lordosis. The implants are designed for use with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each implant grip the endplates of the adjacent vertebrae to resist expulsion. The implants are manufactured from medical grade titanium alloy per ASTM F136 and ASTM F1295.

The SpineView X-Pac Expandable Lumbar Cage System implants are single-use, provided non-sterile, and are intended to be cleaned and steam sterilized

before use. The instruments are re-usable, provided non-sterile, and are intended to be cleaned and steam sterilized before use.

G. Indications for Use / Intended Use

The SpineView X-Pac Expandable Lumbar Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients. The system is designed for use with autogenous bone graft material to facilitate spinal fusion.

The system is intended for use in patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have at least 6 months of non-operative treatment prior to surgery. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via transforaminal approach using autogenous bone graft material. The system is intended for use with supplemental fixation systems cleared for use by the FDA for use in the thoracolumbar spine.

H. Technological Comparison

The technological characteristics of the SpineView X-Pac Expandable Lumbar Cage System implants are similar to the predicate in terms of design, dimensions, intended use, materials, and performance characteristics.

I. Performance Data

Mechanical testing consisting of static and dynamic compression, static and dynamic compression-shear, and subsidence was conducted in accordance with "Class II Special Controls Guidance Document: Intervertebral Fusion Device", June 12, 2007, ASTM F2077, and ASTM F2267 to demonstrate substantial equivalence to the predicate. **animal usability study.**

J. Basis for Substantial Equivalence

The SpineView X-Pac Expandable Lumbar Cage System is similar to the predicate with respect to technical characteristics, performance and intended use. The information provided supports the substantial equivalence of the X-Pac Expandable Lumbar Cage System to the legally marketed predicate.
