DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 4, 2016

SpineVision® S.A.
Sylvain CAVAILLES
Operations Director
10 rue de la Renaissance, Bâtiment E
92160 Antony
FRANCE

Re: K153783
Trade/Device Name: SpaceVision® PLIF, SpaceVision® OLIF, SpaceVision® TLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 31, 2016
Received: April 12, 2016

Dear Sylvain CAVAILLES:

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 Parts 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153783

Device Name
SpaceVision® PLIF, SpaceVision® OLIF, SpaceVision® TLIF

Indications for Use *(Describe)*
The SpaceVision® PLIF (Posterior Lumbar Interbody Fusion), the SpaceVision® TLIF (Transforaminal Lumbar Interbody Fusion) and SpaceVision® OLIF (Oblique Lumbar Interbody Fusion) systems are intervertebral body fusion devices indicated for use with autogenous bone graft in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two continuous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least 6 months of non-operative treatment prior to treatment with SpaceVision® PLIF, SpaceVision® TLIF or SpaceVision® OLIF systems. These devices are to be filled with autogenous bone graft material. These devices can be implanted via posterior or transforaminal approaches. SpaceVision® PLIF, SpaceVision® TLIF or SpaceVision® OLIF systems must be used in combination with supplemental internal spinal fixation which has been cleared by the FDA for use in the lumbar 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

Submitter	SpineVision, S.A. 10 rue de la Renaissance Bâtiment E 92160 Antony - France
Contacts	Sylvain CAVAILLES Operations Director +33 (0)1 53 33 25 98 +33 (0)1.53.33.25.39 (Fax) corp.quality@spinevision.com
Trade Name	SpaceVision® PLIF SpaceVision® OLIF SpaceVision® TLIF
Classification Name	Intervertebral body fusion device
Class	II
Product Code	MAX
CFR section	888.3080
Device panel	Orthopedic
Legally marketed predicate devices	Primary Predicate K082801 Phantom PLIF manufactured by US Spine Additional Predicates P950002 BAK-L manufactured by Zimmer P960025 Brantigan Cage manufactured by DePuy Spine
Description	The SpaceVision® PLIF system (Posterior Lumbar Interbody Fusion), the SpaceVision® OLIF system (Oblique Lumbar Interbody Fusion) and the SpaceVision® TLIF system (Transforaminal Lumbar Interbody Fusion) are intended as an internal spacer between the vertebral bodies of the lumbar (L2-S1) spine to stabilize spinal segment to promote fusion in order to restrict motion and decrease pain. The design of the cages is adapted to the vertebral anatomy. SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF systems consist of cages differentiated by their approach, with varying dimensions and ancillary products for placement of the cages. The systems are supplied sterile or non-sterile. The SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF cages are made from PEEK Optima (Invibio, Inc.) ASTM F2026 and ASTM F560 Tantalum wire. X-ray markers system on the cages permits the identification of cage position and allows post-operative assessment. SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF implants are supplied with their specific instrumentation and trial spacers.

Indications for use	The SpaceVision® PLIF (Posterior Lumbar Interbody Fusion), the SpaceVision® TLIF (Transforaminal Lumbar Interbody Fusion) and SpaceVision® OLIF (Oblique Lumbar Interbody Fusion) systems are intervertebral body fusion devices indicated for use with autogenous bone graft in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two continuous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least 6 months of non-operative treatment prior to treatment with SpaceVision® PLIF, SpaceVision® TLIF or SpaceVision® OLIF systems. These devices are to be filled with autogenous bone graft material. These devices can be implanted via posterior or transforaminal approaches. SpaceVision® PLIF, SpaceVision® TLIF or SpaceVision® OLIF systems must be used in combination with supplemental internal spinal fixation which has been cleared by the FDA for use in the lumbar spine.
Performance data	SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF Devices conform to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007. Mechanical testing includes static axial compression, dynamic axial compression, static compression shear, dynamic compression shear, performed according to ASTM F2077-14, subsidence testing performed according to ASTM F2267-04 and expulsion testing performed according to DRAFT ASTM F-04.25.02.02 (ENDOLAB PI-52 protocol). Results demonstrate comparable mechanical properties to the predicate device. No clinical data has been presented.
Substantial equivalence	SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF Devices are substantially equivalent to the primary predicate Phantom PLIF (K082801 - US Spine) in terms of intended use, material, design, mechanical properties and function. SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF Devices are substantially equivalent to the additional predicates BAK-L (P950002 – Zimmer) and Brantigan Cage (P960025 - DePuy Spine)in terms of intended use and mechanical properties.
Conclusion	SpaceVision® PLIF, SpaceVision® OLIF, and SpaceVision® TLIF Devices are substantially equivalent to the predicate devices.
Date	2016-04-27