May 4, 2018

SpineVision, SAS
% Mr. Donald Guthner
Regulatory Consultant
Orgenix LLC
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K180437
Trade/Device Name: Hexanium® TLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 6, 2018
Received: April 9, 2018

Dear Mr. Guthner:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180437

Device Name
Hexanium® TLIF

Indications for Use *(Describe)*
The Hexanium® TLIF (Transformational Lumbar Interbody Fusion) system is an intervertebral body fusion device 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 Hexanium® TLIF system. This device has to be filled with autogenous bone graft material. This device is implanted via transforaminal approach. Hexanium® TLIF system 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510K SUMMARY

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|---|---|
| Submitter | SpineVision SAS<br>10 rue de la Renaissance<br>Batiment E<br>92160 Antony - FRANCE |
| Submitter Contact | Anaëlla Gallego<br>QA and RA Manager<br>Tel: +33 1 53 33 25 25<br>Fax: +33 1 72 69 00 30<br>EMAIL: a.gallego@spinevision.com |
| Correspondent Contact | Donald W. Guthner<br>ORGENIX LLC<br>111 Hill Road<br>Douglassville, PA 19518<br>USA<br>Tel. +1 646-460-2984<br>Fax. +1 484-363-5879<br>Email: dg@orgenix.com |
| Device Name | Hexanium® TLIF |
| Class | Class II |
| Product Code | MAX: Intervertebral Fusion Device with Bone Graft, Lumbar |
| Classification | 888.3080: Intervertebral body fusion device |
| Device Panel | Orthopedic |
| Primary Predicate device | K153783 – SpaceVision® Interbody Fusion Cages, SpineVision SAS |
| Device Description | The Hexanium® TLIF device is a titanium alloy (Ti6Al4V ELI) interbody cage manufactured via an Additive Manufacturing method. The honeycomb structure allows for bone through-growth through the structure of the device as well as providing lateral and vertical bone graft windows in the body of the cage.<br><br>Hexanium® TLIF is available in heights of 7mm to 16mm in 1mm increments in a Small footprint (28mm X 9mm) or a Medium footprint (32mm X 10.5mm). Hexanium® TLIF has a 5° Lordosis angle.<br><br>Hexanium® TLIF devices are provided sterile. |

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| Indications for Use | The Hexanium® TLIF (Transforaminal Lumbar Interbody Fusion) system is an intervertebral body fusion device 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 Hexanium® TLIF system. This device has to be filled with autogenous bone graft material. This device is implanted via transforaminal approach. Hexanium® TLIF system 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 | The Hexanium® TLIF device conforms to the Class II Special Controls Guidance Document: Intervertebral Body Fusion Device Document issued on June 12, 2007.<br><br>Mechanical testing includes static compression, dynamic compression, static compression shear and dynamic compression shear performed according to ASTM F2077-14, subsidence testing performed according to ASTM 2267-04 and expulsion testing.<br><br>Mechanical testing was performed in a side-by-side comparison to the predicate device.<br><br>Results demonstrate comparable mechanical properties to the predicate device.<br><br>Bacterial Endotoxins Test was performed in accordance to USP to demonstrate that the device meets pyrogen limit specifications. |
| Clinical Performance Data | No clinical data has been presented. |
| Substantial Equivalence | The Hexanium® TLIF is substantially equivalent to the primary predicate device SpaceVision Interbody Fusion Cages in terms of intended use, design, mechanical properties and function. |
| Conclusion | The Hexanium® TLIF is substantially equivalent to the predicate device. |
| Date | 2018-05-03 |