March 10, 2021

SpineVision SAS
℅ Sevrina Ciucci
Regulatory Affairs Consultant
Lince Consulting LLC
111 Deerwood Road, Suite 200
San Ramon, California 94583

Re: K210359
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: February 5, 2021
Received: February 8, 2021

Dear Sevrina 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210359

Device Name
Hexanium® TLIF

Indications for Use *(Describe)*

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.

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

Date Prepared	February 5, 2021
Submitter	SpineVision SAS 10 rue de la Renaissance Batiment E 92160 Antony FRANCE
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Device Name	Hexanium® TLIF
Class	Class II
Product Code	MAX: Intervertebral Fusion Device with Bone Graft, Lumbar
Classification	21 CFR§888.3080: Intervertebral body fusion device
Device Panel	Orthopedic
Primary Predicate	K180437 SpineVision SAS Hexanium® TLIF
Additional Predicate	Nexxt Spine, LLC Matrixx™ System (K171140)

Device Description	The Hexanium® TLIF 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. Hexanium® TLIF is available in a straight and curved shape in heights of 7mm to 16mm in 1mm increments in a Small footprint (28mm x 10mm) and a Medium footprint (32mm x 10mm) for the straight cage and a Small footprint (28mm x 9mm) and a Medium footprint (32mm x 10.5mm) for the curved cage. Hexanium® TLIF has a 5° Lordosis angle. Hexanium® TLIF devices are provided sterile.
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 mechanical testing (according to ASTM 2267-04 and ASTM F2077-14) performed and submitted to support 510(k) clearance of the Hexanium TLIF system (K180437) also supports the subject Hexanium TLIF cages as demonstrated by mechanical and bone fusion worst-case FEA. The results demonstrate that the predicate Hexanium TLIF cage remains a worst-case construct as compared to the subject Hexanium TLIF cage. The predicate Hexanium TLIF (K180437) remains the worst-case construct for mechanical testing because, when compared to the subject cages, the previously tested Hexanium TLIF cage has the highest von mises stress in axial compression, compression shear, torsion, and expulsion. Furthermore, the same predicate cage also has the smallest surface area between the bone graft and endplates and contains the lowest bone graft volume demonstrating it serves as the worst case for bone fusion. Finally, the predicate Hexanium TLIF (K180437) is the worst-case for cleaning and sterilization as is the most difficult-to-clean, has the largest surface area and volume, and has the heaviest weight. The Hexanium® TLIF device conforms to the Class II Special Controls Guidance Document: Intervertebral Body Fusion Device Document issued on June 12, 2007. Bacterial Endotoxins Test was performed in accordance with 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 in terms of intended use, design, mechanical properties, and function.
Conclusion	The Hexanium® TLIF is substantially equivalent to the predicate device.