December 16, 2022

SpineVision, S.A.S.
Ms. Nancy Lincé
President & CEO
Lincé Consulting, LLC
111 Deerwood Road, Suite 200
San Ramon, California 94583

Re: K223251
Trade/Device Name: Hexanium® PLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 20, 2022
Received: October 21, 2022

Dear Ms. Lincé:

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 -S

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)*
K223251

Device Name
Hexanium® PLIF

Indications for Use *(Describe)*
The Hexanium® PLIF (Posterior 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-Sl. 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 PLIF system. This device has to be filled with autogenous bone graft material. This device is implanted via the posterior approach. Hexanium PLIF 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	October 20, 2022
Submitter	SpineVision, S.A.S. 10 rue de la Renaissance Bâtiment E 92160 Antony FRANCE
Submitter Contact	Quang Tran Director, Quality Assurance & Regulatory Affairs Phone: +33 1 53 33 25 25 Email: q.tran@spinevision.com
Correspondent Contact	Nancy Lincé Lincé Consulting, LLC U.S. Agent Regulatory Affairs Consultant Phone: (650) 759-6186 Email: nlince@linceconsulting.com
Device Name	Hexanium® PLIF
Class	Class II
Product Code	MAX: Intervertebral Fusion Device with Bone Graft, Lumbar
CFR Section	21 CFR§888.3080: Intervertebral body fusion device
Device Panel	Orthopedic
Primary Predicate	K210359 SpineVision SAS Hexanium® TLIF
Additional Predicate	K153783 SpineVision SpaceVision® PLIF
Device Description	The Hexanium® PLIF (Posterior Lumbar Interbody Fusion) 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 cage as well as providing lateral and vertical bone graft windows in the body of the cage. Hexanium® PLIF cages are available in heights of 7-16 mm (in 1 mm increments), width of 9 mm, lengths of 22 and 25 mm, and lordosis angles of 0°, 5°, and 8°. Hexanium® PLIF cages are provided sterile and supplied with a set of non-sterile surgical instruments.

Indications for Use	The Hexanium® PLIF (Posterior 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 PLIF system. This device has to be filled with autogenous bone graft material. This device is implanted via the posterior approach. Hexanium PLIF 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	Hexanium® PLIF cages conform to the FDA guidance "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" dated June 12, 2007. Mechanical testing includes static compression, static compression-shear, static torsion, dynamic compression, dynamic compression-shear, and dynamic torsion performed according to ASTM F2077, subsidence testing performed according to ASTM F2267, and expulsion testing performed according to draft ASTM F-04.25.02.02. The Hexanium® PLIF cages meet the same pre-determined functional and performance requirements and external standard requirements as the predicate devices and do not raise any new questions of safety or effectiveness. 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® PLIF is substantially equivalent to the predicate device in terms of intended use, indications for use, design, function, technology, materials, safety, and performance as well as procedural steps, surgical instrumentation, and product labeling.
Conclusion	The Hexanium® PLIF is substantially equivalent to the predicate device.