November 14, 2022

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

Re: K221578
Trade/Device Name: Hexanium® ACIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: October 21, 2022
Received: October 24, 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)*
K221578

Device Name
Hexanium® ACIF

Indications for Use *(Describe)*
The Hexanium® ACIF (Anterior Cervical 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 level from C3-T1. DDD is defined as discogenic neck 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 weeks of non-operative treatment prior to treatment with Hexanium® ACIF system. This device has to be filled with autogenous bone graft material. This device is implanted via an anterior approach.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**K221578**
**510K SUMMARY**

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|---|---|
| **Date Prepared** | October 21, 2022 |
| **Submitter** | SpineVision SAS<br>10 rue de la Renaissance<br>Batiment E<br>92160 Antony<br>FRANCE |
| **Submitter Contact** | Quang Tran<br>Director, Quality Assurance & Regulatory Affairs<br>Tel: +33 1 53 33 25 53<br>Email: q.tran@spinevision.com |
| **Correspondent Contact** | Nancy Lincé<br>Lincé Consulting, LLC<br>US Agent<br>Regulatory Affairs Consultant<br>Phone: (650) 759-6186<br>Email: nlince@linceconsulting.com |
| **Device Name** | Hexanium® ACIF |
| **Class** | Class II |
| **Product Code** | OVE: Intervertebral Fusion Device with integrated fixation, cervical |
| **Classification** | 21 CFR 888.3080: Intervertebral body fusion device |
| **Device Panel** | Orthopedic |
| **Primary Predicate** | SpineVision SAS Hexanium ACIF (K193000) |
| **Device Description** | The Hexanium® ACIF 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® ACIF is available in 2 sagittal profiles (lordotic 6° and convex 6°), heights of 5-12 mm, and 3 footprints (15x12mm, 17x14mm, and 19x15mm). The Hexanium® ACIF screws are self-drilling and available in lengths of 10, 12, 14, and 16mm and diameters of 3.50 and 3.80mm. Hexanium® ACIF is provided sterile. The Hexanium® ACIF system includes a set of reusable surgical instruments. The purpose of this Special 510(k) application is to propose minor modifications to the currently cleared surgical instruments. There are no modifications being proposed for the implantable components of the system. |

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| **Indications for Use** | The Hexanium® ACIF (Anterior Cervical 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 level from C3-T1. DDD is defined as discogenic neck 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 weeks of non-operative treatment prior to treatment with Hexanium® ACIF system. This device has to be filled with autogenous bone graft material. This device is implanted via an anterior approach. |
| **Performance Data** | Appropriate supportive testing and evaluations were conducted on the Hexanium ACIF surgical instruments to demonstrate that they meet product specifications, pertinent standards, medical community's expectations, and product labeling. These evaluations have shown that the modified instrument configurations meet the same pre-determined functional and performance requirements and external standard requirements as the predicate instruments and are substantially equivalent. The Hexanium ACIF implants are unchanged from the predicate and continue to meet special controls FDA guidance "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" dated June 12, 2007. |
| **Clinical Performance Data** | No clinical data has been presented. |
| **Substantial Equivalence** | The Hexanium® ACIF is substantially equivalent to the predicate device in terms of intended use, design, mechanical properties, and function. |
| **Conclusion** | The Hexanium® ACIF is substantially equivalent to the predicate device. |