FloSpine, LLC
℅ Robert A. Poggie, Ph.D.
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame -de-L`lle-Perrot, Quebec J7W3J6
Canada

Re: K223231
Trade/Device Name: Ti-Largo™ Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: January 24, 2023
Received: January 25, 2023

Dear Dr. Poggie:

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)*

K223231

Device Name

Ti-Largo™ Cervical Interbody System

Indications for Use *(Describe)*

Ti-Largo™ Cervical Interbody Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Ti-Largo™ Cervical Interbody Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. Ti-Largo™ Cervical Interbody Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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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510(k) SUMMARY for the Ti-Largo™ Cervical Interbody System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of the Ti-Largo™ Cervical Interbody System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	October 18, 2022

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	FloSpine, LLC
Manufacturer Address:	3651 FAU Blvd, Suite 400 Boca Raton, FL 33431 USA
Registration Number:	3010125671
Contact Name:	Peter Harris
Title:	President / CEO
Device Trade Name:	Ti-Largo™ Cervical Interbody System
Device Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral Body Fusion Device - Cervical
Classification Code:	ODP
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.3080

PRIMARY PREDICATE DEVICE

K193255	FloSpine Largo™ PEEK Interbody System

PREDICATE DEVICE

K193359	Additive Implants, Inc., SureMAX Family of Cervical Spacers

DEVICE DESCRIPTION

FloSpine Ti-Largo™ Cervical Interbody Cages are keystone shaped devices that have a central lumen and smaller graft windows throughout the structure of the implant. The implants are additively manufactured (ADM) using grade 23 titanium alloy powder per ASTM F3001. The implants are provided sterile (gamma radiation, 25 kGy minimum dose), are intended for single use only, and should not reused under any circumstances. Components from this system should not be used in conjunction with components from other company products.

Ti-Largo™ Cervical Interbody Cages are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the cervical spine. The Ti-Largo™ Cervical Interbody System was developed for anterior cervical fusion with implants available in keystone shaped footprints ranging in size between 11 x 14mm and 16 x 18mm, thickness ranging from 5 to 14mm in 1 mm increments, 7-degree lordosis for all sizes, and 0-degree lordosis for the smallest and largest sizes. The surface texture of the 3D structure of the implants resists expulsion forces.

INDICATIONS FOR USE

Ti-Largo™ Cervical Interbody Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Ti-Largo™ Cervical Interbody Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. Ti-Largo™ Cervical Interbody Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

TECHNOLOGICAL CHARACTERISTICS

The Ti-Largo™ Cervical Interbody System has similar technological characteristics as the primary predicate and predicate devices, including the materials, design, function, range of sizes, manufacturing processes, surgical technique, and indications for use.

The indications for use for the subject and primary predicate devices are identical except for the tradename of the implant. The general shape, footprints, thickness, and lordosis options are the same or similar for the subject and predicate and devices; the additively manufactured titanium material is the same (ADM, grade 23 titanium alloy powder per F3001) to that of the predicate device. The minor differences in manufacturing and technology were assessed per the FDA guidance document for spinal devices with the outcomes of mechanical and physical testing passing all acceptance criteria and supportive of substantial equivalence.

PERFORMANCE DATA

The following tests were performed:

1. Static Compression per ASTM 2077
2. Dynamic Compression fatigue per ASTM F2077
3. Static Torsion per ASTM 2077
4. Dynamic Torsion fatigue per ASTM F2077
5. Static Expulsion
6. Subsidence per ASTM F2267
7. Wear Debris Analysis

Sterilization validation with SAL of 10^{-6} is based on the VD_{max} method recommended by the ISO and AAMI (ANSI/AAMI/ISO 11137-1 and ANSI/AAMI/ISO 11137-2).

CONCLUSIONS

The data presented in this 510(k) notification show the Ti-Largo™ Cervical Interbody System to be substantially equivalent to the cited legally marketed predicate devices. It has the same or similar technological characteristics, materials, sizes, manufacturing processes, and principles of operation as the predicate devices. Therefore, The Ti-Largo™ Cervical Interbody System is substantially equivalent to the predicate devices.