February 20, 2020

FloSpine, LLC
% Robert A. Poggie, PhD
President
BioVera Inc.
65 Promenade Saint-Louis
Notre-Dame-de-L'Ile-Perrot, QC, J7V 7P2
Canada

Re: K193255
Trade/Device Name: Largo™ PEEK Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: November 22, 2019
Received: November 26, 2019

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 L. Showalter, PhD
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193255

Device Name
Largo™ PEEK Interbody System

Indications for Use *(Describe)*

Largo™ Interbody Cages - Cervical 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. Largo™ Interbody Cages - Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Largo™ Interbody Cages - Cervical 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.

Largo™ Interbody Cages - Lumbar are indicated for use with autograft bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Largo™ Interbody Cages - Lumbar are intended to be used with supplemental spinal fixation systems, such as pedicle screws. Patients should be skeletally mature and have six (6) months of non-operative therapy 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY for FloSpine Largo™ PEEK 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 Largo™ PEEK Interbody System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7V 7P2, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone Number:	514-901-0796
Fax Number:	514-901-0796
Date of Submission:	November 22, 2019

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:	Largo™ PEEK Interbody System
Device Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral Body Fusion Device - Cervical Intervertebral Body Fusion Device - Lumbar
Classification Code:	MAX, ODP
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.3080

C. PRIMARY PREDICATE DEVICE

K143479	Tides Medical Bluefin Interbody Fusion System

D. DEVICE DESCRIPTION

The Largo™ PEEK Interbody System consists of a variety of hollow vertebral body spacers designed for use in the cervical and lumbar spine. The devices are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine and cervical spine.

The Largo™ PEEK Interbody Cervical Cage was developed for anterior cervical fusion and is available in footprints from 14 x 12mm up to 17 x 14mm and at 0 and 7 degree lordosis. The cages are trapezoidal in shape and include x-ray markers for positioning. The subject device is with angular teeth to allow the implant to grip the superior and inferior end plates to provide resistance to expulsion.

The Largo™ PEEK Posterior Lumbar Interbody Cage (PLIF) was developed for posterior stabilization of the lumbar spine. These cages feature a convex bullet nose design and an axial void designed to contain autograft material. The subject device is made in various lengths and designed with angular teeth to allow the implant to grip the superior and inferior end plates to provide resistance to expulsion. The devices range from 7mm to 16mm in height, 23mm to 37mm in length, and from 9 to 11mm in width.

The Largo™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF) Cage was developed for posterior stabilization of the lumbar spine. It is a banana-shaped implant featuring a convex, bullet nose design and an axial void designed to hold autograft material. The subject device is made in various lengths and designed with angular teeth to allow the implant to grip the superior and inferior end plates to provide resistance to expulsion. The devices range from 7mm to 16mm in height and footprints of 11 x 28 up to 13 x 37 mm. The cages incorporate an A/P lordotic angle of 5 degrees.

The Largo™ PEEK Anterior Lumbar Interbody Fusion (ALIF) Cage was developed for anterior stabilization of the lumbar spine. The footprint is oval in shape and features a center beam for additional strength. The leading edge is bulleted for ease of insertion and features angular teeth for endplate grip and resistance to expulsion. The devices range from 8mm to 22mm in height and footprints of 30 x 24 up to 47 x 30 mm. The cages incorporate an A/P lordotic angle of 6 or 12 degrees.

The Largo™ PEEK Lateral Lumbar Interbody Fusion (LLIF) Cage was developed for a lateral approach to the lumbar spine. The cage is rectangular in shape and features a center beam for additional strength. The leading edge is bulleted for ease of insertion and features angular teeth for endplate grip and to resist expulsion. The devices range from 8mm to 16mm in height and footprints of 18 x 50 mm up to 22 x 60 mm. The cages incorporate an A/P lordotic angle of 0 or 6 degrees.

E. MATERIALS

Largo™ PEEK devices are made from Solvay's Zeniva® ZA-500 Medical Grade PEEK that conforms to ASTM F2026. The tantalum rods are manufactured from tantalum conforming to ASTM F560.

F. INDICATIONS FOR USE

Largo™ Interbody Cages - Cervical 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. Largo™ Interbody Cages - Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Largo™ Interbody Cages - Cervical 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.

Largo™ Interbody Cages - Lumbar are indicated for use with autograft bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Largo™ Interbody Cages - Lumbar are intended to be used with supplemental spinal fixation systems, such as pedicle screws. Patients should be skeletally mature and have six (6) months of non-operative therapy prior to treatment with an intervertebral cage.

G. TECHNOLOGICAL CHARACTERISTICS

The Largo™ PEEK Interbody System has the identical technological characteristics as the predicate device, including the materials, design, function, range of sizes, manufacturing processes, surgical techniques, and intended use.

H. 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 per ASTM F1839-08
6. Subsidence per ASTM F2267
7. Wear Debris Analysis

Sterility was validated per AAMI TIR33:2005 Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization and Sterilization of health care products - Radiation sterilization-Substantiation of 25 kGy as a sterilization dose - Method VDmax for a sterility assurance level (SAL) of 10^{-6}.

I. CONCLUSIONS

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