FloSpine
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7V7P2
Canada

April 7, 2021

Re: K210182
Trade/Device Name: PANAMA™ Anterior Cervical Plate (ACP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 21, 2021
Received: January 25, 2021

Dear Robert 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,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210182

Device Name
PANAMA™ Anterior Cervical Plate (ACP) System

Indications for Use *(Describe)*

The FloSpine PANAMA™ Anterior Cervical Plate System is intended for anterior cervical screw fixation of the cervical spine at levels C2-T1. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

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) SUMMARIES

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following is a summary of safety and effectiveness of the PANAMA™ Anterior Cervical Plate 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:	January 21, 2021

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:	PANAMA™ Anterior Cervical Plate (ACP) System
Device Common Name:	Appliance, fixation, spinal intervertebral body
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Code:	KWQ
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.3060

C1. PRIMARY PREDICATE DEVICE

K060442	K2M - Pyrenees Cervical Plate System

C2. ADDITIONAL PREDICATE DEVICE

K022344	Zimmer/Centerpulse - Trinica Select Anterior Cervical Plate

C3. REFERENCE DEVICE

K141850	FloSpine Canaveral Pedicle Screw System

D. DEVICE DESCRIPTION

The PANAMA™ Anterior Cervical Plate System is an anterior cervical spine fixation system that provides cervical spine fixation for intervertebral disk replacement procedures. The PANAMA™ ACP System is designed to stabilize and facilitate fusion in intervertebral disk replacement surgeries.

The PANAMA™ Anterior Cervical Plate (ACP) System consists of cervical plates that are 2.25 mm thick, 16 mm wide, and length options between 18 and 110 mm (end-to-end length) to accommodate 1 to 5 levels of fusion between C2 and T1. The PANAMA ACP System includes fixed and variable angle screws with 4.0mm and 4.5mm diameters and length options between 12mm and 20mm with self-tapping and self-drilling options. The screws and plates are made from Ti-6Al-4V ELI conforming to ASTM F-136.

The plates and screws of the PANAMA™ ACP System include a primary and secondary mechanism to mitigate screw backout. The primary mechanism consists of a cover plate that is rotated in-situ that partially covers the screw. The secondary mechanism consists of a number of radial teeth on the screw head and mating grooves on the underside of the cover plate. In the event that the screws start to back out, the teeth and grooves will engage, thereby preventing further counter-clockwise rotation of the screw. The screws in the system have a threaded hole at the bottom of the drive to provide easy insertion and positioning during surgery. The PANAMA™ ACP System of implants and instruments is provided clean and non-sterile in one sterilization case.

E. INDICATIONS FOR USE

The FloSpine PANAMA™ Anterior Cervical Plate System is intended for anterior cervical screw fixation of the cervical spine at levels C2-T1. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

F. TECHNOLOGICAL CHARACTERISTICS, COMPARISON TO PREDICATE DEVICE

The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System has similar technological characteristics as the predicate devices, including the materials, design, function, range of sizes, manufacturing processes, surgical techniques, and intended use. The minor differences in design and sizing options do not present new issues of

safety and effectiveness. Specifically, the following characteristics are the same or similar for the subject and predicate devices:

- The subject and predicate device K022344 are made of Ti6Al4V (ASTM F136)
- The subject and predicate device K060442 are indicated for anterior cervical fixation for 1 through 5 levels.
- The subject and predicate device K022344 are indicated for levels C2 – T1.
- The subject and predicate devices include fixed and variable angle screws and self-tapping and self-drilling screws.
- The biomechanical performance characteristics of the subject and predicate devices were assessed and determined acceptable per ASTM F1717.

G. PERFORMANCE DATA

Performance testing of the PANAMA™ ACP System was performed per ASTM F1717 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model". Testing included static axial compression bend testing, dynamic axial compression testing, and static torsion testing. The testing verified achievement of the acceptance criteria for the subject device. The following tests were performed:

1. Static axial compression bending testing per ASTM 1717-18.
2. Static torsion testing per ASTM 1717-18.
3. Dynamic compression bend testing per ASTM 1717-18.

The results of testing demonstrated the subject device to possess similar strength and mechanical performance characteristics as the predicate devices.

The PANAMA™ ACP System of implants and instruments are provided clean, not sterile to the end user in a single tray and case system. Sterility of the subject device system was verified for a SAL of 10^{-6} per AAMI TIR12-2004, ISO 17664-2004.

H. CONCLUSIONS

The data presented in these 510(k) notifications show the FloSpine PANAMA™ Anterior Cervical Plate (ACP) System to be substantially equivalent to the cited legally marketed predicate and reference devices.