October 19, 2023

FloSpine, LLC
% Robert Poggie, PhD
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'Ile-Perrot, QC J7W3J6
Canada

Re: K232484
Trade/Device Name: KeyLift™ Expandable Interlaminar Stabilization System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: August 15, 2023
Received: August 16, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin O'neill -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232484

Device Name

KeyLift™ Expandable Interlaminar Stabilization System

Indications for Use *(Describe)*

The FloSpine KeyLift™ Expandable Interlaminar Stabilization System is a posterior non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (Tl-S1). It is intended for plate fixation/attachment to the spinous processes/lamina for the purpose of achieving supplemental fusion in the following conditions: Lumbar spinal stenosis, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The KeyLift™ Expandable Interlaminar Stabilization System is intended for use with allograft or autograft bone and is not intended for stand-alone use.

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
KeyLift™ Expandable Interlaminar Stabilization System

In accordance with 21 CFR 807.92, the following information is a 510(k) summary of the KeyLift™ Expandable Interlaminar Stabilization System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-de-L'Ile-Perrot, Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone Number:	514-901-0796
Date of Submission:	August 15, 2023

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:	KeyLift™ Expandable Interlaminar Stabilization System
Device Common Name:	Spinous process plate
Classification Name:	Spinal interlaminal fixation orthosis
Classification Code:	PEK
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.3050

PRIMARY PREDICATE DEVICE

K153302	Paradigm Spine Coflex-IF

ADDITIONAL PREDICATE DEVICE

K130438	X-spine Axle Interspinous Fusion System

DEVICE DESCRIPTION

The KeyLift™ implant is an expandable, interlaminar stabilization device that is implanted posteriorly between the lamina and spinous processes of the thoracic and lumbar region. The implant features an expanding distal end which increases the height between the vertebral bodies. The superior and inferior wings are crimped to the spinous process, and a clamp is attached to the implant for final fixation. The components of the KeyLift™ system of implants and reusable instruments are manufactured from titanium alloy per ASTM F136 and stainless steel per ASTM F138 and A564. KeyLift™ implants are available in a range of sizes to accommodate surgeon and patient needs. Both the KeyLift implant and KeyLift Clamp are provided pre-assembled.

INDICATIONS FOR USE

The FloSpine KeyLift™ Expandable Interlaminar Stabilization System is a posterior non-pedicle supplemental fixation device intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes/lamina for the purpose of achieving supplemental fusion in the following conditions: Lumbar spinal stenosis, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The KeyLift™ Expandable Interlaminar Stabilization System is intended for use with allograft or autograft bone and is not intended for stand-alone use.

SUBSTANTIAL EQUIVALENCE

The KeyLift™ Expandable Interlaminar Stablization System is substanially equivalent to the predicate devices in terms of intended use, indications for use, design, materials, and mechanical performance. Differences in design to not raise different questions of safety and effectiveness.

PERFORMANCE DATA

Axial dynamic and static compression, static and dynamic offset torsion, static axial torsion, static and dynamic compression-bending, retaining ring pushout, and axial pull-off testing demonstrated substantially equivalence mechanical performance. Worst-case implants were identified using FEA and/or engineering analyses. Surgeon-user cadaver evaluation demonstrated the KeyLift™ system of implants and instruments performs as described in the surgical technique and instructions for use.

CONCLUSIONS

The data presented in this 510(k) notification demonstrate that the KeyLift™ Expandable Interlaminar Stabilization System is substantially equivalent to the predicate devices.