May 27, 2020

Joline GmbH & Co. KG
% Robert Poggie
President
BioVera Inc.
65 Promenade Saint Louis
Notre-Dame-del-L'Ile-Perrot, CA J7V 7P2 QC

Re: K192449
Trade/Device Name: Joline® Kyphoplasty System Allevo
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope; Cement, Bone Vertebroplasty
Regulatory Class: Class II
Product Code: HRX, NDN
Dated: April 24, 2020
Received: April 27, 2020

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,

for

Jesse Muir, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K192449

Device Name

Joline® Kyphoplasty System Allevo

Indications for Use *(Describe)*

The Joline Kyphoplasty System Allevo is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethylmethacrylate (PMMA) bone cements).

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.

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510(k) Summary for the Joline® Kyphoplasty System Allevo

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 Joline® Kyphoplasty System Allevo.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, Quebec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	April 24, 2020

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Joline GmbH & Co. KG
Manufacturer Address:	Neue Rottenburger Strasse 50, 72379 Hechingen, Germany
Registration Number:	3004734264
Contact Name:	Peter Kohlbecher
Title:	Director Sales & Marketing
Device Trade Name:	Joline® Kyphoplasty System Allevo
Device Common Name:	Vertebroplasty System; Inflatable Bone Tamp
Classification Names:	Arthroscope; Cement, Bone, Vertebroplasty
Classification Codes:	NDN and HRX
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.1100 and 888.3027

C1. PRIMARY PREDICATE DEVICE

K150607	Osseoflex SB

C2. REFERENCE DEVICE

K140937	Osseoflex SB

D. DEVICE DESCRIPTION

The Joline® Kyphoplasty System Allevo is a sterile, single-use system of instruments that facilitates balloon kyphoplasty. The subject device includes both single and double balloon catheter options that allows the introduction of one, or two balloons, into each pedicle at a time, for a total of two or four balloons per vertebrae. The balloons can be expanded or deflated separately using contrast medium, a balloon adapter, and an inflation device. The Joline® Kyphoplasty System Allevo includes instruments and accessories that facilitate the kyphoplasty procedure, including devices and curettes for creation of access channels within the bone. Subsequent to creating the cavities within the vertebral bone, the vertebral body is stabilized with an FDA cleared PMMA bone cement that cures within a few minutes. The Joline Kyphoplasty System Allevo is offered in kits that are comprised of various combinations of instruments that address surgeon preference and specific clinical condition of the patient.

E. INDICATIONS FOR USE

The Joline® Kyphoplasty System Allevo is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethylmethacrylate (PMMA) bone cements).

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Joline® Kyphoplasty System Allevo has similar device characteristics and clinical indications for use as the predicate device. The table below compares the technical and performance characteristics of the subject, reference, and predicate devices. The subject and predicate devices are comprised of instruments that facilitate balloon kyphoplasty in the spine, including balloons for creating cavities within bone, cannula to transfer saline, means to deliver FDA cleared bone cement, means to create a channel of access within the bone, and are single use and provided sterile.

Performance Characteristic	Requirement (Joline, Single Balloon 22/16)	Requirement (Predicate Osseoflex)	Test Result and Conclusion
Balloon Burst Pressure and Volume (Constrained)	Burst Pressure ≥ 27 bar (≈ 400 psi) Burst Volume ≥ 6 ml	Burst Pressure ≥ 27 atm (≈ 400 psi) Burst Volume ≥ 4 ml	Passed all conditions Equivalent to predicate
Tensile Force Balloon – Shaft	Detachment Force ≥ 15 N	Bond tensile strength ≥ 15 N	Passed all conditions Equivalent to predicate
Tensile Force Hub – Shaft	Detachment Force ≥ 15 N	Bond tensile strength ≥ 15 N	Passed all conditions Equivalent to predicate
Tensile Force Luer Lock	Detachment Force ≥ 15 N	Bond tensile strength ≥ 15 N	Passed all conditions Equivalent to predicate
Balloon Inflation Behavior (Unconstrained Balloon Compliance)	Average Diameter 16 mm Length Change: least possible Balloon Diameter ≤ 19 mm Balloon working length ≤ 24mm	Balloon Diameter ≤ 19 mm Balloon working length ≤ 24 mm	Passed all conditions Equivalent to predicate

G. PERFORMANCE DATA

The following tests were performed in support of the substantial equivalence determination.

Test Performed	Acceptance Criteria
Balloon Burst Pressure	Burst pressure (p_{burst}) ≥ 27 bar (≈ 400 psi)
Balloon Burst Volume	Burst volume (V_{burst}) ≥ 3 ml
Balloon Inflation Behavior	Inflated with 6 ml, the average diameter of the balloon should be 16 mm
Tensile Force Balloon-Shaft	Minimum tensile strength ($F_{balloon-shaft}$) ≥ 15 N
Tensile Force Hub-Shaft	Minimum tensile strength ($F_{hub-shaft}$) ≥ 15 N
Balloon Repeated Inflation	The balloon must not burst within 3 inflation/deflation cycles
Balloon Deflation Time	Deflation time (t_{def}) ≤ 3 s

The results of the non-clinical tests show that the inflatable bone tamp of the Joline Kyphoplasty System Allevo meets or exceeded all performance requirements.

H. CONCLUSION

The Joline® Kyphoplasty System Allevo is substantially equivalent to the identified predicate device based on the indications for use, materials, design, and performance data presented in this 510(k) notification.