September 12, 2024

Field Orthopaedics
℅ Robert Poggie
President of BioVera, Inc., Regulatory Consultant to Field Orthopaedics
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'Ile-Perrot, QC J7W3J6
Canada

Re: K241695
Trade/Device Name: Extremity All Suture System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HTY, HWC
Dated: August 23, 2024
Received: August 23, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241695

Device Name

Extremity All Suture System

Indications for Use *(Describe)*

The Extremity All Suture System is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

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) #: K241695

510(k) Summary

Prepared on: 2024-09-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Field Orthopaedics
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Correspondent Address	65 Promenade Saint Louis, Notre-Dame-de-L'Ile-Perrot, QC, J7W3J6 Canada
Correspondent Contact Telephone	5143497226
Correspondent Contact	Robert A Poggie, PhD
Correspondent Contact Email	orthobob@biovera.ca

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Extremity All Suture System
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number	888.3040
Product Code(s)	MBI, HTY, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151230	Arthrex FiberTak Anchors	MBI
K112237	MicroSuture Anchors	HWC
K180348	Field Orthopaedics Micro Screw System - FO Pin and Wire Kit	HTY

Device Description Summary

21 CFR 807.92(a)(4)

The Extremity All Suture System (EASS) includes the Griplasty™ System – Base of Thumb and Griplasty™ System – Micro, Mini and Small Suture Anchor. The system incorporates soft tissue fixation devices; 'all suture' anchors with an expandable push-in design, provided preloaded in an inserter handle with associated single-use instruments, and supplied sterile (ethylene oxide) for single use. The EASS anchors are constructed from a hollow braid with a suture component assembled through the hollow braid.
All sutures, inclusive of suture line and anchor, are made with non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE) per

ASTM F2848. All needles are made with Stainless Steel per ASTM F899. The instrumentation is made from medical grade stainless steel and medical grade Acrylonitrile Butadiene Styrene (ABS). The anchor and connected sutures are impacted into a pilot hole. The sutures are manually tensioned to set the anchor by bunching the suture sleeve.

Griplasty™ System – Base of Thumb: Comprises a suture anchor implant (with or without needles) and associated instrumentation for use in carpometacarpal (CMC) joint arthroplasty.

Griplasty™ System – Micro, Mini and Small Suture Anchor: Comprises a range of all suture anchor implants (with or without needles) and associated instrumentation for use in securing soft tissue to bone.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Extremity All Suture System is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Extremity All Suture System (EASS) indications for use are the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Extremity All Suture System (EASS) has the same intended use, basic technological and design characteristics and materials as the predicate device. Any differences between the EASS and the predicate are considered minor and do not raise questions concerning safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical testing of the worst-case size anchors of the EASS was performed per the FDA Guidance Document for Suture Anchors, ASTM F543-17, and ASTM F1839-08. Engineering analysis indicated that the smallest anchor was worst-case (least resistance to pull-out force). Acceptance criteria were based on similar sized predicate suture anchor devices. The results of mechanical testing, which included statistical analysis and comparison of subject and predicate device pull-out loads, showed the subject device to have non-inferior (i.e. similar / 'substantially equivalent') pull-out load and performance as the predicate devices.

Based on the intended use, technological characteristics, and data submitted, Field Orthopaedics, Pty. Ltd. has determined that its Extremity All Suture System is substantially equivalent to currently marketed predicate devices.