Field Orthopaedics Pty. Ltd.
% Robert Poggie, Ph.D.
President
BioVera Inc.
65 Promenade Saint Louis
Notre-Dame-del-L'Ile-Perrot, J7V 7P2 Ca

July 17, 2018

Re: K180348
Trade/Device Name: Field Orthopaedics Micro Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: June 1, 2018
Received: June 4, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180348

Device Name
Field Orthopaedics Micro Screw System

Indications for Use *(Describe)*

The Field Orthopaedics Micro Screw System consists of the following kits with the following indications:

The FO Micro Screw Kit is intended for fixation of fractures, osteotomies, and arthrodeses of small bones in the foot, hand, and forearm.

The FO Pin and Wire Kit is intended for fixation and stabilization of bone fractures or as guidance at insertion of implants into the skeletal system.

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

Field Orthopaedics Micro Screw 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 Field Orthopaedics Micro Screw 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:	July 12, 2018

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Field Orthopaedics Pty. Ltd.
Manufacturer Address:	375 Wickham Terrace Spring Hill, 4000 QLD, Australia
Registration Number:	
Contact Name:	Christopher Jeffery, B.ENG (Hons), GCE, Lead, MBBS
Title:	CEO
Device Trade Name:	Field Orthopaedics Micro Screw System
Device Common Name:	Metallic bone screw; Kirschner wire (K-Wire)
Classification Name:	Smooth or threaded metallic bone fixation fastener;
Classification Codes:	HWC, HTY – Class II
Classification Panel:	Orthopaedic
Regulation Number:	21 CFR section 888.3040

C. PREDICATE AND REFERENCE DEVICES

C1: Primary Predicates Devices:

K051567	Medartis, Inc	Aptus 1.2 Cortical Screw Aptus 1.2 Hand	APTUS Titanium Fixation System
K100736	SMT Schilling Metailtechnik GmbH	0.6 - 2.0 mm Single and Double Trocar Pins and K-Wires	Orthopaedic Fixation Pins and Wires / Kirschner / Guide Wires

C2: Reference Devices:

K121425	Wright Medical Technology, Inc.	Titanium Alloy (ASTM F136) Bone Screws	ORTHOLOC 3Di Ankle Fusion Plating System and ORTHOLOC Bone Screws
K143050	Smith & Nephew, Inc.	Cobalt-Chromium Alloy K-Wires	VLP FOOT Plating, Screw System and Accessories
K050681	TriMed Inc.	1.7mm CCS	Omnitech and Easylock Osteosystem
K124027	Apogee OrthoSolutions, LLC	Monster Screw System	Monster Screw System

D. DEVICE DESCRIPTION

The Field Orthopaedics Micro Screw System is an extremity trauma system consisting of the FO Micro Screw Kit and the FO Pin and K-Wire Kit.

The FO Micro Screw Kit includes 1.5 mm and 2.0 mm diameter cannulated compression screws with lengths ranging from 6 mm to 16 mm in 1 mm increments and 0.6 mm single trocar K-wires of length 70 mm. Accompanying the screws is a specifically designed instrument kit, tailored to the insertion of the 1.5 and 2.0 FO Micro Screw.

The FO Pin and K-Wire Kit includes 0.6, 0.8, 1.0 and 1.2 mm double trocar K-wires of length options 70 mm and 150 mm; and 1.6 and 2.0 mm double trocar Pins of length 150 mm. Accompanying the FO Pins and K-Wires are appropriately sized guide sleeves to aid insertion.

Materials: All Field Orthopaedics Micro Screws are made from Titanium Alloy (ASTM F136).

All Field Orthopaedics Pins and K-Wires are made from Stainless Steel Alloy (ASTM F138).

The instrumentation is made from medical grades stainless steel, anodized aluminium, and marked with epoxy resin.

E. INTENDED USE

The Field Orthopaedics Micro Screw System consists of the following kits with the following indications:

The FO Micro Screw Kit is intended for fixation of fractures, osteotomies, and arthrodeses of small bones in the foot, hand, and forearm.

The FO Pin and Wire Kit is intended for fixation and stabilization of bone fractures or as guidance at insertion of implants into the skeletal system.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The FO Micro Screw Kit includes 1.5 mm and 2.0 mm diameter cannulated compression screws with lengths ranging from 6 mm to 16 mm in 1 mm increments and 0.6 mm single trocar K-wires of length 70 mm. Accompanying the screws is a specifically designed instrument kit, tailored to the insertion of the 1.5 and 2.0 FO Micro Screw.

The FO Pin and K-Wire Kit includes 0.6, 0.8, 1.0 and 1.2 mm double trocar K-wires of length options 70 mm and 150 mm; and 1.6 and 2.0 mm double trocar Pins of length 150 mm. Accompanying the FO Pins and K-Wires are appropriately sized guide sleeves to aid insertion.

The materials, length and diameter options, and indications for use of the FO Micro Screws, Pins and K-Wires were compared to those of the predicate devices and determined to be substantially equivalent.

G. PERFORMANCE DATA

Performance analysis of the FO micro screw was conducted through theoretical engineering analyses and mechanical testing methods. Engineering analyses were performed on the FO Micro screw, Trimed CCS 1.7, and Aptus Hand 1.2. Mechanical testing of the FO Micro Screws was performed per ASTM F543. More specifically, the torsional strength, maximum torque to drive-in and remove the screws, and pull out force were determined for the worst-case size and length of FO Micro Screw, and compared to predicate devices. The results of mechanical testing and engineering analysis showed the subject device to possess greater strength than the predicate devices, and meet the strength requirements for (solid) screws (ASTM F543). Simulated surgeon-user testing per the prescribed surgical technique showed the FO Micro Screw System to perform as intended.

H. CONCLUSION

The Field Orthopaedics Micro Screw System is substantially equivalent to the identified predicate devices based on the indications for use, materials, design, length and diameter options, and performance data presented in this 510(k) application.