March 23, 2020

Field Orthopaedics Pty Ltd.
Kieran Leacy
Senior Regulatory Advisor
375 Wickham Terrace
Spring Hill, 4000 Australia

Re: K200043
Trade/Device Name: Field Orthopaedics Bony Trauma Extremity System (BTES) Plate Range and Plate Screws.

Field Orthopaedics Bony Trauma Extremity System (BTES) Screw Range.

Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 20, 2019
Received: January 8, 2020

Dear Kieran Leacy:

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,

Shumaya Ali, M.P.H.
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)*
K200043

Device Name
Field Orthopaedics Bony Trauma Extremity System (BTES) Screw Range

Indications for Use *(Describe)*
The Field Orthopaedics BTES Screw Range is intended for use in the fixation of fractures, osteotomies, and arthrodesis, appropriate for the size of the device, in adults and in both, children (2-12 years) and adolescents (12- 21 years), in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The FO Fenestrated Screws are not for the delivery of bone graft, bone cement or bone void filler.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K200043

Device Name
Field Orthopaedics Bony Trauma Extremity System (BTES) Plate Range and Plate Screws

Indications for Use *(Describe)*
The Field Orthopaedics BTES Plate Range and Plate Screws are intended for use in the fixation of fractures, osteotomies and arthrodesis of the hand and other small bones. The system may be used in both adults and paediatric patients.

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)

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510(k) SUMMARY

Field Orthopaedics Bony Trauma Extremity 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 Bony Trauma Extremity System.

A. SUBMITTERS INFORMATION

Submitter Name:	Field Orthopaedics Pty. Ltd.
Submitter Address:	375 Wickham Terrace Spring Hill, 4000 QLD, Australia
Contact Person:	Kieran Leacy
Phone Number:	+614 0269 3021
Fax Number:	+1 514-901-0796 c/o Robert Poggie, Phd
Date of Submission:	March 15, 2020

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Field Orthopaedics Pty. Ltd.
Manufacturer Address:	375 Wickham Terrace Spring Hill, 4000 QLD, Australia
Registration Number:	3015131017
Contact Name:	Kieran Leacy
Title:	Senior Regulatory Affairs Advisor
Device Trade Name:	Field Orthopaedics Bony Trauma Extremity System (BTES) Plate Range and Plate Screws. Field Orthopaedics Bony Trauma Extremity System (BTES) Screw Range.
Device Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Codes:	HRS - Class II HWC - Class II
Classification Panel:	Orthopaedic
Regulation Number:	21 CFR section 888.3030 21 CFR section 888.3040

Predicates

Plating System Primary Predicate: **K051567** - Aptus Titanium Fixation System, Medartis

Screw system Primary Predicate: **K180348** - FO Micro Screw System, Field Orthopaedics Pty Ltd

Additional Predicates

K083447, Anchorage Plating System, Stryker
K090522, Hand Plating System, Osteomed
K141527, variable Angle Locking Hand System, Depuy Synthes
K161616, DePuy Synthes 2.4 mm Cannulated Screws, Depuy Synthes

D. DEVICE DESCRIPTION

The Field Orthopaedics Bony Trauma Extremity System (BTES) is an extremity trauma system consisting of a range of screws and a range of plates.

The BTES screw range consists of a range of screws intended for standalone use, and a range of screws intended to be used with the BTES plate range. The standalone screw range consists of 1.2 mm solid, partially threaded screws of various lengths; 1.5 – 5.0 mm Cannulated, partially threaded screws in both headless and headed designs of various lengths; and 2.0 – 3.0 mm Cannulated, fenestrated, partially threaded screws in both headless and headed designs of various lengths. The range of screws intended to be used with the BTES plate range consists of 1.2, 1.5 and, 2.0 mm solid, fully-threaded screws of various lengths.

The BTES plate range consists of a variety of configurations including straight, L, T, and H frames. Key features of the plate range include anatomical contouring, locking screw, rotational correction, and compression holes. The plate thickness ranges from 0.6 – 1.2 mm with a number of holes ranging from 1 – 16 holes.

Materials: All screws in the screw range are made with Titanium ELI(as per ASTM F136).

All plates are available as identical configurations in both Titanium ELI (as per ASTM F136) and CP Titanium (ISO 5832-2).

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

E. INDICATIONS FOR USE

The Field Orthopaedics BTES Screw Range is intended for use in the fixation of fractures, osteotomies, and arthrodesis, appropriate for the size of the device, in adults and in both, children (2-12 years) and adolescents (12- 21 years), in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The FO Fenestrated Screws are not for the delivery of bone graft, bone cement or bone void filler.

The Field Orthopaedics BTES Plate Range and Plate Screws are intended for use in the fixation of fractures, osteotomies and arthrodesis of the hand and other small bones. The system may be used in both adults and paediatric patients.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Field Orthopaedics Bony Trauma System is substantially equivalent to the predicate fracture fixation systems because they are manufactured from similar materials and have similar design features. The subject system differs because the components contain slightly different geometry.

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The devices have the same indications, are available by prescription only, and are provided non-sterile for single-use only. In addition, the performance data, device description, and comparison to the predicate devices demonstrate that the subject device, the Field Orthopaedics Bony Trauma Extremity System, is substantially equivalent to the identified predicate devices.

G. PERFORMANCE DATA

ASTM F382 static four-point bend testing was performed against predicates. ASTM F543 torsion testing, pullout strength testing and insertion torque testing was performed against predicates. The results of mechanical and user testing, and theoretical analysis demonstrate the Field Orthopaedics Bony Trauma Extremity System to be substantially equivalent to the identified predicate devices. The acceptance criteria for the mechanical testing were all met, supporting the overall conclusion of substantial equivalence for the Bony Trauma Extremity System.

H. CONCLUSION

Based on the indications for use, materials, design similarities, and performance data presented in this 510(k) application, it can be concluded that the Field Orthopaedics Bony Trauma Extremity System is as safe and as effective device and the predicate devices and is substantially equivalent.