February 16, 2023

Field Orthopaedics Pty Ltd
Jillianne Mckenzie
Vice President, Regulatory Affairs
30 Florence St
Teneriffe, QLD 4005
Australia

Re: K230118
Trade/Device Name: Bony Trauma Extremity System (BTES) Screw Range
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 16, 2023
Received: January 17, 2023

Dear Jillianne Mckenzie:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230118

Device Name
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.

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 pediatric 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k) Summary - Field Orthopaedics Bony Trauma Extremity System Screw Range, NX Nail 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 Bony Trauma Extremity System (BTES) Screw Range, NX Nail System.

A. SUBMITTER'S INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	January 16, 2023

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Field Orthopaedics Pty Ltd
Manufacturer Address:	30 Florence Street, Teneriffe 4005 QLD AUSTRALIA
Registration Number:	3015131017
Contact Name:	Jillianne McKenzie
Title:	Vice President, Regulatory Affairs
Device Trade Names:	Bony Trauma Extremity System (BTES) Screw Range
Device Common Names:	Screw, Fixation, Bone
Classification Names:	Smooth or threaded metallic bone fixation fastener
Classification Codes:	HWC - Class II
Classification Panel:	Orthopedic
Regulation Numbers:	21 CFR sections 888.3040

PRIMARY PREDICATE DEVICE

K200043	Field Orthopaedics Bony Trauma Extremity System (BTES) Plate Range and Plate Screws and Field Orthopaedics Bony Trauma Extremity System (BTES) Screw Range

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 cleared in K200043.

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 purpose of this Special 510(k) device modification is to notify FDA of the sterile NX Nail System, which is a line extension to the BTES Screw Range described above and cleared in K200043. NX Nail implants are made from the same titanium alloy using the same manufacturing processes as BTES implants, are non-compressive in design, and are available in lengths ranging from 12 to 90 mm and diameters ranging from 2.0 to 5.0 mm. NX Nail implants are offered non-sterile and sterile (gamma radiation). This Special 510(k) also includes added instruments for implanting NX Nail devices.

Materials: All BTES screws in the Screw Range are made with Titanium alloy ELI (as per ASTM F136). All plates are available as identical configurations in both Titanium alloy ELI (as per ASTM F136) and CP Titanium (ISO 5832-2). Instruments are made from medical grades stainless steel, anodized aluminum, and marked with epoxy resin.

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 pediatric patients.

TECHNOLOGICAL CHARACTERISTICS

The Bony Trauma Extremity System (BTES) Screw Range, NX Nail System line extension, is substantially equivalent to the primary predicate device, the Field Orthopaedics Bony Trauma Extremity System (BTES), because they are manufactured from the same materials using the same manufacturing processes, and possess the same indications and intended uses. The NX Nail System line extension is within the design scope, intended and indicated uses for the BTES, and the updated instruments are within the scope of the cleared indicated use. The table below compares the technological characteristics.

<table>
<tr><th></th><th>Subject Device, BTES Screw Range, NX Nail System, K230118</th><th colspan="2">Primary Predicate Device, FO BTES Screw Range and Plate Range, K200043</th></tr>
<tr><td>Reg, product code</td><td>888.3040, HWC</td><td colspan="2">888.3040, HWC; 888.3030, HRS</td></tr>
<tr><td>Indication For Use</td><td>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 pediatric patients.</td><td colspan="2">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 pediatric patients.</td></tr>
<tr><td>Type</td><td>Non-Compressive Headless</td><td colspan="2">Compression Head and Headless</td></tr>
<tr><td>Cannulated</td><td>Yes</td><td colspan="2">Yes and No</td></tr>
<tr><td>Self-Drilling</td><td>Yes</td><td colspan="2">Yes</td></tr>
<tr><td>Inner/Outer Diameter
For compression head and headless</td><td rowspan="2">NX Nail:

2.0 to 5.0mm in diameter,

12 to 90mm in length</td><td>Fenestrated:
2.0 to 3.0mm diam.
6 to 60mm long</td><td>Micro:
1.2 to 2.0 mm diam.
6 to 16 mm long</td></tr>
<tr><td>Length
For compression head and headless</td><td>Compression:
1.2 to 5.0 mm
6 to 90 mm long</td><td>Nano:
1.2 mm diam.
6 to 20 mm long</td></tr>
<tr><td>Material</td><td>Titanium Alloy (F136)</td><td colspan="2">Titanium Alloy (F136)</td></tr>
<tr><td>Sterile</td><td>Yes and No (NX Nail); No (Remaining components of BTES Screw Range, NX Nail System)</td><td colspan="2">No (BTES in K200043)</td></tr>
</table>

Comparison of the technological characteristics and indicated use of the subject and primary predicate devices demonstrate that the subject device, the BTES Screw Range, NX Nail System, is substantially equivalent to the primary predicate device.

PERFORMANCE DATA

Verification and validation (V&V) activities included the following:

- Engineering analyses of NX Nail implants for bending strength and pull out force relative to cleared BTES demonstrated no new worst case,
- Insertion, removal, and maximum torques of NX Nail implants were measured and met acceptance criteria,
- Cleaning, packaging, and sterilization validations for the sterile NX Nail met acceptance criteria,
- Surgeon user evaluation demonstrated the NX Nail devices to work as intended, and
- Assessment of biocompatibility of instruments and implants, packaging, and distribution requirements for the subject devices met acceptance criteria.

CONCLUSION

The data presented in this Special 510(k) device modification show the BTES Screw Range, NX Nail System, is substantially equivalent to the legally marketed primary predicate device, the Field Orthopaedics Bony Trauma Extremity System (BTES). It has the same or similar technological characteristics, materials, sizes, manufacturing processes, and principles of operation as the primary predicate device.