September 5, 2023

Innovate Orthopaedics Limited
Mike Bilson
QA/RA Manager
The Globe, Bridge Street, Slaithwaite
Huddersfield, HD7 5JN
United Kingdom

Re: K231819
Trade/Device Name: Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 19, 2023
Received: June 21, 2023

Dear Mike Bilson:

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,

Jesse Muir -S

Jesse Muir, Ph.D.
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)*
K231819

Device Name

Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw

Indications for Use *(Describe)*

Quick-Start Screws are indicated for interference fixation of soft tissue grafts and/or bone-tendon-bone grafts for ligament reconstruction such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K231819

Innovate Orthopaedics Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw

Date Prepared: June 19, 2023

Submitter Information

Submitter: Innovate Orthopaedics Limited
Address: The Globe, Bridge Street, Slaithwaite
HD7 5JN, United Kingdom
Contact: Mike Bilson
Telephone: +44 (0) 1484 796796
Email: mike.bilson@innovateortho.co.uk

Device Information

Trade Name: Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw
Common Name: Screw, Fixation, Bone, Orthopedics
Classification: Class II
Regulation: 21 CFR 888.3040
Classification Name: Smooth or threaded metallic bone fixation fastener
Classification Panel: Orthopedics
Product Code: HWC

Predicate Information

Trade Name: Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw
Common Name: Screw, Fixation, Bone, Orthopedics
Classification: Class II
Regulation: 21 CFR 888.3040
Classification Name: Smooth or threaded metallic bone fixation fastener
Classification Panel: Orthopedics
Product Code: HWC
510(k) Number: K212547

Purpose of Submission

This traditional premarket notification is submitted to obtain clearance for the modified Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw, which includes the modification to include MR conditional labelling.

Predicate Device Information

The predicate Innovate Orthopaedics Quick-Start Orthopaedic Fixation Screw family of products are interference screws indicated for interference fixation of soft tissue grafts and/or bone-tendon-bone grafts for ligament reconstruction. The screw is composed of medical grade titanium alloy and is supplied sterile for single use in both standard thread and reverse thread designs. This is identical to the proposed device.

Device Description

The Innovate Orthopaedics Quick-Start Orthopaedic Fixation Screw family of products are interference screws indicated for the fixation of soft tissue or bone-tendon-bone grafts in ligament reconstruction procedures. The screw is composed of medical grade titanium alloy and is supplied sterile for single use in both standard thread and reverse thread designs.

Accessory Descriptions

The Innovate Orthopaedics Quick-Start Guide-Wire accessory is composed of medical grade nickel-titanium alloy and is supplied sterile for single use. The Guidewire is 1.8mm in diameter and 250mm in length.

The Innovate Orthopaedics Quick-Start 3.5 Hex Cannulated Screwdriver is composed of a high-grade stainless-steel shaft with a silicon rubber soft-grip handle. The screwdriver is supplied non-sterile and is cleaned and sterilized at the customer facility.

Intended Use

The Quick-Start Orthopaedic Fixation Screw/Reverse Thread Screw are indicated for interference fixation of Bone-Tendon-Bone or soft tissue grafts in ligament reconstruction.

Indications for Use

Quick-Start Orthopaedic Screws are indicated for interference fixation of soft tissue grafts and/or bone-tendon-bone grafts for ligament reconstruction such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions.

Technological Characteristics

The Technological characteristics of the modified Quick-Start Orthopaedic Fixation Screws are unchanged from the previously cleared Quick-Start Orthopaedic Fixation Screws (K212547):

The following are the key technological characteristics of the devices:

- Manufactured from Titanium Ti6-AL4-V ELI alloy per ASTM F-136.

- The driver interface of 3.5 mm hex.
- Cannulated for use with guide wire accessories.
- Variable, or graduated, lead in thread to ease insertion.
- The head has a flat beveled edge head profile with a thread starter marker.

Comparison of Principles of Operation & Technological Characteristics

The modified Quick-Start Screws and original Quick-Start Screws have the same intended use, indications, technological characteristics and principal of operation.

Performance Data

The Quick-Start screws did not require clinical study data since substantial equivalence to the currently marketed predicate device was demonstrated with the following attributes:

- Indications for Use
- Technological characteristics
- Non-clinical performance testing including MR Safety testing

Non-clinical MR safety testing has been completed on the Quick-Start Screw. Tests for displacement force and torque effects, heating effects and image artifacts were conducted on three sizes of Quick-Start Screw, in accordance with FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", dated May 20, 2021 and ASTM F2052-21, ASTM F2213-17, ASTM F2182-19 and ASTM F2119-07(2013).

Results of the testing confirmed that the risk of displacement force or torque effects during clinical MR scanning is considered low and acceptable. Results also established the potential temperature increase and image artefact during clinical MR scanning and demonstrate the safety of the Quick-Start Screws in the MR environment within the conditions specified in the Instructions for Use.

The addition of MR conditional labelling does not raise different questions of safety or effectiveness.

Conclusion

Based on the indications for use, technological characteristics, and the summary of data submitted, Innovate Orthopaedics has determined that the modified Quick-Start Orthopaedic Fixation Screws are substantially equivalent to the currently marketed predicate device. The Quick-Start Orthopaedic Fixation Screws continue to perform as well as the predicate device.