December 30, 2021

Innovate Orthopaedics Limited
Alex Gutteridge
Managing Director
3M Buckley Innovation Centre
Firth Street
Huddersfield, HD1 3BD
United Kingdom

Re: K212547
Trade/Device Name: Quick-Start Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 11, 2021
Received: August 13, 2021

Dear Alex Gutteridge:

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,

for

Laura C. Rose, 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)*
K212547

Device Name
Quick-Start Screws

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.

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510(k) Summary

Innovate Orthopaedics Quick-Start Screw

Date Prepared: August 11, 2021

Submitter Information

Submitter: Innovate Orthopaedics Limited
Address: 3M Buckley Innovation Centre
Firth Street, Huddersfield, HD1 3BD
Contact: Alex Gutteridge
Telephone: +44 (0) 1484 505869
Email: alex.gutteridge@innovateortho.co.uk

Device Information

Trade Name: Quick-Start Screws
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

Purpose of Submission

This traditional premarket notification is submitted to obtain initial clearance for the Quick-Start Screw and Reverse Thread Screw. This is a new device to the United States market.

Predicate Device Information

The Quick-Start Screw and Reverse Thread Screw described in this submission are substantially equivalent to the following predicate device: Smith & Nephew, Inc. RCI Fixation Screws (K992945).

Device Description

The Innovate Orthopaedics Quick-Start 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 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 nonsterile and is cleaned and sterilized at the customer facility.

Intended Use

The Quick-Start 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 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.

Comparison of Principles of Operation & Technological Characteristics

The Quick-Start device family and RCI Fixation Screws have the same intended use and principal of operation. The proposed and predicate devices have similar indications for use; the minor differences in indications for use do not constitute a new intended use for the device. The Quick-Start device family and RCI Fixation Screws have similar technological characteristics, differences include: variable pitch on the lead-in taper, flat beveled edge on screw head, and a wider range of screw sizes. The minor differences between the proposed and predicate devices do not raise different questions of safety or effectiveness and are therefore substantially equivalent.

Performance Data

A comparative biophysical performance study of the Quick-Start Screws compared to a legally marketed device was carried out using 10 fresh-frozen human cadaveric knees. The Quick-Start Screw was found to be easier to engage with the bone tunnel and initially insert than the comparative device while still achieving similar immediate postsurgical fixation strength. This study provides objective evidence that the subject device is substantially equivalent to a legally marketed predicate.

Testing according to the applicable ASTM standards demonstrated that the Quick-Start Orthopaedic Fixation Screws meet the performance based requirements outlined by the FDA including torsional strength (ASTM F543), driving torque (ASTM F543), axial pullout strength. This testing demonstrates the subject device is as safe and effective as currently marketed screws.

The Quick Start Screws were analyzed for endotoxin using the Limulus Amebocyte Lysate (LAL) test. Testing demonstrates that the subject devices meet the acceptance criteria at 20 endotoxin

units per device in accordance with USP for medical devices which are not in contact with cerebrospinal fluid.

The Quick Start Screws were determined to be biocompatible per International standard: ISO 10993-1, Biological *Evaluation of Medical Devices - Part 1: Evaluation and Testing* and FDA Guidance Document: *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1": Evaluation and Testing within a risk management process* issued September 4, 2020, the Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screws are categorized as an implant device with permanent contact (>30 days) to tissue or bone.

The devices are supplied sterile for single-use. The Quick Start screws are provided sterile (SAL 10^{-6}) by means of Co60 gamma irradiation. The Quick Start Screws have a 5 year shelf life.

Conclusion

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