April 24, 2025

Newclip Technics
% J.D. Webb
President
The OrtoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K250155
Trade/Device Name: Xpert Knee
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: January 15, 2025
Received: January 21, 2025

Dear J.D. Webb:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250155

Device Name

Xpert Knee

Indications for Use *(Describe)*

The implants of Xpert Knee range are indicated for the fixation of fractures, non-unions and malunions of the proximal tibia in adults.

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.

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"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."

K250155
510(k) Summary
Xpert Knee

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the Xpert Knee range.

1. Submitter:

NEWCLIP TECHNICS
P.A. de la Lande Saint Martin
45 rue des Garottières
F-44115 Haute-Goulaine - France
Telephone: (33) 2 28 21 37 12

Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven. UT 84401
Telephone: 512-590-5810

2. Trade name: Xpert Knee

Common Name: Plate, Fixation, Bone / Screw, Fixation, bone

Product code: HRS - Plate, Fixation, Bone
HWC - Screw, Fixation, Bone

Classification Name: Single/multiple component metallic bone fixation appliances and accessories. (21 CFR part. 888.3030)

Smooth or threaded metallic bone fixation fastener.(21 CFR part. 888.3040)

3. Primary predicate or legally marketed devices which are substantially equivalent:

- DEPUY SYNTHES 3.5 mm VA LCP® Proximal Tibia Plate System (K120689) - **Primary Predicate Device**
- DEPUY SYNTHES 3.5 mm LCP® Medial Proximal Tibia Plates (K050646) - **Additional Predicate Device**
- DEPUY SYNTHES 3.5 mm LCP® Proximal Tibia Plates (K082624) - **Additional Predicate Device**
- DEPUY SYNTHES 3.5 mm LCP® Proximal Tibia Plates (K011978 / K030597) - **Additional Predicate Device**

Reference devices:

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- Newclip Technics Footmotion Plating System range (K221395)
- Newclip Technics Activmotion S (K241539)
- Newclip Technics Activmotion (K173746)

4. Description of the device: The Xpert Knee range consists of plates and screws designed for the fixation of fractures, non-unions and malunions of the proximal tibia in adults.

The plates and screws of the Xpert Knee range will be provided sterile by gamma sterilization or non-sterile for sterilization by health care professionals prior to use.

The instruments of the Xpert Knee range will be provided non sterile for sterilization by health care professionals prior to use.

Materials: CP Titanium grade 4 (conform to ASTM F67 and ISO 5832-2) for the plates, and Titanium alloy Ti-6Al-4V ELI (conform to ASTM F136 and ISO 5832-3) for the screws.

Function: The implants of Xpert Knee range are indicated for the fixation of fractures, non-unions and malunions of the proximal tibia in adults.

5. Technological characteristics and substantial equivalence

The Xpert Knee range has the same or similar technological characteristics of the predicate devices.

The Xpert Knee range has the same or similar technological characteristics of the predicate devices.

6. Indication for use

The implants of Xpert Knee range are indicated for the fixation of fractures, non-unions and malunions of the proximal tibia in adults.

7. Summary of the technological characteristics compared to predicate

Indication for use
The implants of Xpert Knee range are indicated for the fixation of fractures, non-unions and malunions of the proximal tibia in adults.

Material
The Xpert Knee range uses the same material as the primary predicate devices.

Design
The Xpert Knee range and the predicates are substantially equivalent in terms of shape, and operating principles.

Sizes
The Xpert Knee range and the predicates are substantially equivalent in their dimensions.

8. Non-clinical Test Summary:

The following tests were conducted:

- Engineering analysis and comparative static and dynamic tests were performed on the plates, according to ASTM F382.
- Engineering analysis regarding pullout strength and comparative torsional test were performed on the screws, according to ASTM F543.

The analysis showed that the Xpert Knee range is substantially equivalent to cleared predicates.

9. Clinical Test Summary:

No clinical studies were performed.

10. Conclusions Non-clinical and clinical:

The Xpert Knee range is as safe, as effective, and performs as well or better than the legally marketed devices identified above**.**