July 28, 2026

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

Re: K261511
Trade/Device Name: Xpert Ankle
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: May 6, 2026
Received: May 7, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261511

Please provide the device trade name(s).

Xpert Ankle

Please provide your Indications for Use below.

The implants of the Xpert Ankle range are intended for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

NEWCLIP-TECHNICS

510 (k) Summary
Xpert Ankle range

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

1. Submitter:

NEWCLIP TECHNICS

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Telephone: (33) 2 28 21 37 12

Contact Person:

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

2. Trade name: Xpert Ankle

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)

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

- NEWCLIP TECHNICS Activ Ankle (K173641) - **Primary Predicate Device**
- Arthrex Fracture Plates (K151732) - **Additional Predicate Device**
- DEPUY SYNTHES 3.5 mm LCP® Distal Tibia T-Plates (K080522) - **Additional Predicate Device**

Reference devices:

- Newclip Technics Xpert Knee (K250155)
- Newclip Technics Xpert Wrist (K213214)
- Newclip Technics Xpert Hand (253906)

4. **Description of the device:**

The Xpert Ankle range consists of pre-contoured tibial and fibula plates and screws in various sizes designed for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

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

The instruments of the Xpert Ankle will be provided nonsterile for sterilization by health care professionals prior to use.

Single use kits (Initial A Xpert) contain implants and instruments provided sterile by gamma sterilization.

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 the Xpert Ankle range are indicated for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

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5. Indications for use:

The implants of the Xpert Ankle range are intended for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

6. Summary of the technological characteristics compared to predicate

The Xpert Ankle range is substantially equivalent to the predicate devices in intended use, design, manufactured materials, and mechanical performance.

The following tests and analyses were conducted:

- Engineering analysis (static) and dynamic fatigue testing were performed on the worst-case plate in accordance with ASTM F382, with the results compared to the Arthrex Fracture Plates (K151732) predicate device.

- Torsional strength and driving torque were performed on the worst-case screw in accordance with ASTM F543, with the results evaluated against the minimum performance criteria specified in FDA's Guidance document, Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway (2020).

- Pullout strength was evaluated through engineering analysis using the Chapman (1996) equation, as specified in the FDA Guidance, with the results evaluated against the guidance's minimum acceptable values.

7. Clinical Test Summary:

No clinical studies were performed.

8. Conclusions Nonclinical:

Newclip Technics considers the Xpert Ankle range to be equivalent to the predicate devices listed above. This conclusion is based upon the device's similarities in principles of operation, technology, materials, and indications for use.