



May 29, 2026

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

Re: K261038

Trade/Device Name: Xpert PFP  
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: March 30, 2026  
Received: March 30, 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](mailto: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.

K261038

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Please provide the device trade name(s).

?

Xpert PFP

Please provide your Indications for Use below.

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The implants of the Xpert PFP range are indicated to the fixation of fractures (including periprosthetic fractures), mal-unions, non-unions, and osteotomies of the femur in adults.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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## **510 (k) Summary Xpert PFP range**

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

**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:

- Zimmer NCB® Periprosthetic Femur Plate System ( K120772) - **Primary Predicate Device**
- DEPUY SYNTHES LCP Distal Femur Plate (K062564) - **Additional Predicate Device**
- KINAMED SuperCable Grip and Plate System: SuperCable Trochanteric Grips (K072250) - **Additional Predicate Device**

### Reference devices:

- Newclip Technics Activmotion S (K241539)
- Newclip Technics Xpert Knee (K250155)

**4. Description of the device:** The Xpert PFP range consists of plates and screws in various sizes designed for the fixation of fractures (including periprosthetic fractures), mal-unions, non-unions, and osteotomies of the femur in adults.

The plates and screws of the Xpert PFP range will be provided sterile by gamma sterilization.

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

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

**Function:** The implants of the Xpert PFP range are indicated to the fixation of fractures (including periprosthetic fractures), mal-unions, non-unions, and osteotomies of the femur in adults.

### 5. Technological characteristics and substantial equivalence

The Xpert PFP range has the same or similar technological characteristics as the predicate devices.

### 6. Indication for use



The implants of the Xpert PFP range are indicated to the fixation of fractures (including periprosthetic fractures), mal-unions, non-unions, and osteotomies of the femur in adults.

## **7. Summary of the technological characteristics compared to predicate**

### *Indication for use*

The Indications for Use for the Xpert PFP range are similar to the predicate devices.

### *Material*

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

### *Design*

The Xpert PFP range and the predicates are substantially equivalent in terms of shape, and operating principles. The modular trochanteric extension plate differs from the predicate's modular design because of the interface mechanism and hook design.

### *Sizes*

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

## **8. Non-clinical Test Summary:**

The following tests were conducted:

- Engineering analysis, comparative ASTM F382 static and dynamic tests plate four-point bend testing, and comparative fatigue construct testing was performed on the plates, trochanteric extension, and screws.
- Engineering analysis regarding comparative torsional test was performed on the screws, according to ASTM F543.

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

## **9. Clinical Test Summary:**

No clinical studies were performed.

## **10. Conclusions Non-clinical and clinical:**

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