



November 24, 2021

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

Re: K213214

Trade/Device Name: Xpert Wrist
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: September 23, 2021
Received: September 29, 2021

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 (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,



Shumaya Ali -S

Shumaya Ali, MPH
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

510(k) Number (if known)

K213214

Device Name

Xpert Wrist

Indications for Use (Describe)

The implants of the Xpert Wrist range are intended for the fixation of hand and forearm fractures, osteotomies and arthrodeses 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.

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510 (k) Summary for the Xpert Wrist range

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

Summary preparation date: August, 2021

1. Submitter:

NEWCLIP TECHNICS
P.A. de la Lande Saint Martin
45 rue des Garottières
F-44115 Haute-Goulaine - France
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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 Wrist

Common Name:

Plate, Fixation, Bone / Screw, Fixation, bone

Product code:

HRS - Plate, Fixation, Bone (primary)

HWC - Screw, Fixation, Bone

Classification Name:

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

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

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

- Alians Fragment Specific of Newclip Technics (K170843)

Additional predicate or legally marketed devices which are substantially equivalent:

- Trimed Bone Plates of Trimed (K060041),
- Synthes (USA) LCP Wrist Fusion Plates of Synthes (K042355),
- APTUS® Wrist 2.5 System of Medartis (K142906 and K172170),
- APTUS Titanium Fixation System of Medartis (K051567),
- Skeletal Dynamics Protean Fragment Plate System (K140372),
- Geminus Volar Distal Radius Plate System (K182492),
- Acumed Wrist Spanning Plate (K131764),
- Activ Ankle of Newclip Technics (K143061 and K173641),
- High Tibial Osteotomy System of Newclip Technics (K141548)

4. Description of the device: The Xpert Wrist range consists of plates and screws, designed for the fixation of hand and forearm fractures, osteotomies and arthrodeses in adults.

The implants of the Xpert Wrist range will be provided non sterile for sterilization by health care professionals prior to use, or provided sterile by gamma sterilization.

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

Materials:

CP Titanium (conform to ASTM F67 and ISO 5832-2) and Titanium alloy Ti-6Al-4V ELI (conform to ASTM F136 and ISO 5832-3).

Function:

The implants of the Xpert Wrist range are intended for the fixation of hand and forearm fractures, osteotomies and arthrodeses in adults.

5. Substantial equivalence claimed to predicate devices:

The Xpert Wrist is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.

6. Intended use:

The implants of the Xpert Wrist range are intended for the fixation of hand and forearm fractures, osteotomies and arthrodeses in adults.

7. Summary of the technological characteristics compared to predicate

Intended Use

The implants of the Xpert Wrist range are intended for the fixation of hand and forearm fractures, osteotomies and arthrodeses in adults.

Material

The Xpert Wrist range uses the same material as the predicate devices.

Design

The Xpert Wrist range and the predicates are equivalent in terms of shape, material, and operating principles.

Sizes

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

8. Non-clinical Test Summary:

The following tests were conducted:

1. 4-point-bending tests per ASTM F382 were conducted to compare the bending strength of the subject device plates to the predicates.
2. ASTM F543 torsional testing was performed on the subject screws.
3. Equation described by Chapman for axial pull-out strength was performed on the subject screws (FDA-Guidance: Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway-2020).
4. Endotoxin testing is performed using LAL quantitative kinetic chromogenic method.

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



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K213214

9. Clinical Test Summary:

No clinical studies were performed.

10. Conclusions Non-clinical and clinical:

Based on the indications for use, technological characteristics, and the summary of data submitted, Newclip Technics determined that the Xpert Wrist range is substantially equivalent to the cleared predicate devices listed above.