



July 30, 2024

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

Re: K241539

Trade/Device Name: Activmotion S
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 30, 2024
Received: May 31, 2024

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.

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

for

Shumaya Ali, M.P.H.
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

Submission Number (if known)

K241539

Device Name

Activmotion S

Indications for Use (Describe)

The implants of the Activmotion range are indicated for knee osteotomy 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 **Activmotion S range**

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

1. Submitter:

NEWCLIP TECHNICS

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F-44115 Haute-Goulaine - France
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: Activmotion S

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:

- Activmotion range of Newclip Technics (K173746)

Reference predicate or legally marketed devices which are substantially equivalent:

- TomoFix® Osteotomy System of DEPUY SYNTHES (K141796)
- Surfix® Knee Osteotomy System of SURFIX TECHNOLOGIES (K041601).

4. Description of the device: The Activmotion S range consists of plates and screws in various sizes designed for knee osteotomy in adults.

The Activmotion S range consists of pre-contoured tibial and femoral plates and screws in various sizes designed for knee osteotomy in adults.

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

The instruments of the Activmotion S 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).

Function: The implants of the Activmotion range are indicated for knee osteotomy in adults.

5. Technological characteristics and substantial equivalence:

The Activmotion S have the same or similar technological characteristics of the predicate device.

6. Indications for use:

The implants of the Activmotion range are indicated for knee osteotomy in adults.

7. Summary of the technological characteristics compared to predicate

Indications for Use

The implants of the Activmotion range are indicated for knee osteotomy in adults as the predicate devices.

Material

The Activmotion S range uses the same material as the primary predicate devices.

Design

The Activmotion S range and the predicates are equivalent in terms of shape and operating principles.

Sizes

The Activmotion S range and the predicates are 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.
- Engineering analysis regarding pullout strength and comparative torsional test were performed on the screws.

The analysis showed that the Activmotion S range is substantially equivalent to cleared predicates.

9. Clinical Test Summary:

No clinical studies were performed.

10. Conclusions Non-clinical and clinical:

The Activmotion S range is as safe, as effective, and performs as well or better than the legally marketed device identified above.