



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

NEWCLIP TECHNICS
% Mr. J.D. Webb
Official Correspondent
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

January 30, 2015

Re: K141548
Trade/Device Name: High Tibial Osteotomy System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 24, 2014
Received: December 29, 2014

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K141548

Device Name

High Tibial Osteotomy System

Indications for Use (Describe)

The High Tibial Osteotomy System is indicated for fixation of high tibial osteotomy.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



NEWCLIP-TECHNICS

4. **510 (k) Summary for the High Tibial Osteotomy System**

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the High Tibial Osteotomy System.

Summary preparation date: January 26, 2015

1. Submitter:	Contact Person:
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	J.D. Webb The OrthoMedix Group, Inc. 1001 Oakwood Blvd Round Rock, TX 78681 Telephone: 512-388-0199
2. Trade name:	High Tibial Osteotomy System
Common Name:	Plates for high tibial osteotomy Screws for high tibial osteotomy
Class:	II
Product code:	HRS/HWC
Classification Name:	Plate, Fixation, Bone (21 CFR part. 888.3030) Screw, Fixation, Bone (21 CFR part. 888.3040)

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

- The Arthrex Titanium Opening Wedge Osteotomy System of Arthrex, Inc. (K032187),
- The Surfix[®] Knee Osteotomy System of Surfix Technologies S.A. (K041601),
- The Humerus Locking Plating System of Newclip Technics (K063095).

**4. Description of the device:**

The High Tibial Osteotomy System consists of a pre-contoured plate and self-tapping screws in various sizes for high tibial osteotomy. The plates and screws are manufactured from titanium alloy and color anodized. The High Tibial Osteotomy System will be provided sterile.

Materials:

Titanium alloy Ti-6Al-4V ELI (conform to ASTM F 136-12a and/or ISO 5832-3).

Function:

The implants of the High Tibial Osteotomy System are indicated for fixation of high tibial osteotomy.

5. Substantial equivalence claimed to predicate devices:

The High Tibial Osteotomy System is substantially equivalent to the Arthrex Titanium Opening Wedge Osteotomy System of Arthrex, Inc. (K032187), to the Surfix[®] Knee Osteotomy System of Surfix Technologies S.A. (K041601) and to the Humerus Locking Plating System of Newclip Technics (K063095) in terms of intended use, design, materials used, mechanical safety and performance.

6. Intended use:

The High Tibial Osteotomy System is indicated for fixation of high tibial osteotomy.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative fatigue compression tests.
- Comparative static compression tests.
- Geometric analysis of the subject and predicate screws.
- Torsional engineering analysis of plates.

8. Clinical Test Summary:

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical:

The High Tibial Osteotomy System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.