August 28, 2019

Neosteo
℅ Mr. J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4314 W. 3800 S.
West Haven, Utah 84401

Re: K191424
Trade/Device Name: Interphalangeal Joint Fusion Device Range
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 8, 2019
Received: August 12, 2019

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. 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,

for RPJ

Ronald Jean, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191424

Device Name

Interphalangeal Joint Fusion Device Range

Indications for Use *(Describe)*

The Interphalangeal Joint Fusion Devices are intended for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PSC Publishing Se
443-6740 EF

510(k) Summary

I. SUBMITTER'S INFORMATION

A. *510(k) Owner*

NEOSTEO

Mallève 2A

1 Boulevard Jean Moulin

44 100 Nantes, France

Tel: +33 (0)2 36 56 96 70

Fax: +33 (0)2 51 70 61 34

B. *Contact Person*

JD Webb

The Orthomedix Group, Inc.

4314 W. 3800 S.

West Haven, UT 84401

Tel: 512 590 5810

Email: jdwebb@orthomedix.net

C. *Date of Preparation of the 510(k) Summary*

8th August 2019

II. DEVICE IDENTIFICATION

Trade or proprietary name	Interphalangeal Joint Fusion Device Range
Common or usual name	Interphalangeal Joint Fusion Device Range
Classification regulation	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener
Proposed Regulatory Class	Class II
Panel	87 "Orthopedic"
Product code	HWC
Primary Predicate Device	HammerFix® (K133636) from Extremity Medical
Secondary Predicate Devices	ProToe® (K101165) from Wright Medical Kirschner and Guide Wires (K100736) from SMT Schilling Metalltechnik GmbH

neosteo
EFFICIENT MOBILITY

510(k) Summary

III. DEVICE DESCRIPTION

The Interphalangeal Joint Fusion Device Range consists of metallic devices intended to stabilize two bone fragments until bone fusion. They are available in several lengths and angulations.
All the implants are made of titanium alloy.

A. Materials

Titanium alloy per ISO 5832-3 / ASTM F136.

IV. INDICATIONS FOR USE

The Interphalangeal Joint Fusion Devices are intended for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

V. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

Intended Use	The Interphalangeal Joint Fusion Devices and all the predicates have similar intended uses.
Materials	The Interphalangeal Joint Fusion Devices are fabricated of the same material as the predicate devices.
Design Features/Functions	The Interphalangeal Joint Fusion Devices and the cited predicate devices share similar basic design features and functions.
Dimensions	The Interphalangeal Joint Fusion Devices are dimensionally similar to the cited predicate devices.
Sterilization	The Interphalangeal Joint Fusion Devices are provided sterile as are the cited predicate devices.
Performance Specification	Mechanical testing confirmed the Interphalangeal Joint Fusion Devices demonstrated as good or better performances than the cited predicate devices under the same test conditions.

VI. NON-CLINICAL TEST SUMMARY

The following mechanical tests were performed:

- Static bending test
- Dynamic bending test

- Axial pull-out test

The results of these tests indicate that the Interphalangeal Joint Fusion Devices are as strong or stronger than predicate devices.

VII. CLINICAL TEST SUMMARY

No clinical studies were performed.

VIII. CONCLUSIONS NON-CLINICAL AND CLINICAL

NEOSTEO considers the Interphalangeal Joint Fusion Devices to be equivalent to the predicate devices listed above. This conclusion is based on the devices' similarities in principles of operation, technology, materials and indications for use.