February 11, 2022

Neosteo
% J.D. Webb
Official Correspondent
The Orthomedix Group, Inc.
4314 W. 3800 S.
West Haven, Utah 84401

Re: K212545
Trade/Device Name: FlexitSystem® Knee Osteotomy System
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: January 12, 2022
Received: January 18, 2022

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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212545

Device Name
FlexitSystem® Knee Osteotomy system

Indications for Use *(Describe)*
The FlexitSystem® plates and screws system is indicated for proximal tibial and distal femoral osteotomies.

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

I. SUBMITTER'S INFORMATION

A *510(k) Owner*

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

11th February 2022

II. DEVICE IDENTIFICATION

Trade or proprietary name	FlexitSystem® Knee osteotomy system
Common or usual name	FlexitSystem® plates and screws
Classification regulation	21 CFR 888.3030 (plates) [primary] 21 CFR 888.3040 (screws)
Proposed Regulatory Class	Class II
Panel	87 "Orthopedic"
Product code	HRS [primary] HWC

Primary Predicate Device	Tomofix® small stature (K100676) from Synthes USA
Additional Predicate Devices	Surfix® Knee osteotomy system (K041601) from Surfix Technologies SA TomoFix Osteotomy System(K023941) from Synthes USA. TomoFix Medial Distal Femur Plates (K081353) from Synthes USA.
Reference device	ActivMotion Range (K173746) from Newclip Technics

III. DEVICE DESCRIPTION

The FlexitSystem® Knee osteotomy system range consists of metallic surgical devices intended to maintain opening and closing wedge osteotomies of the proximal tibia and distal femur. They are available in several lengths and shapes. A FlexitSystem® Knee osteotomy system consists of:

- A Neosteo plate;
- Neosteo screws that are locked into the

plate. All the implants are made of titanium alloy.

Fixation of the plate is ensured by the threading of the holes in the plate and the corresponding threads on the screws for a complete fixation of the implant.

A. Materials

Titanium alloy per ISO 5832-3 / ASTM F136.

IV. INDICATIONS FOR USE

FlexitSystem® plates and screws system is indicated for proximal tibial and distal femoral osteotomies.

V. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

Intended Use	The FlexitSystem® Knee osteotomy system and all the predicates have similar intended uses.
Materials	The FlexitSystem® Knee osteotomy system is fabricated of the same or similar material as the predicate devices.
Design Features/Functions	The FlexitSystem® Knee osteotomy system and the cited predicate devices share similar basic design features and functions.
Dimensions	The FlexitSystem® Knee osteotomy system is dimensionally similar to the cited predicate devices.

Sterilization	The FlexitSystem® Knee osteotomy system is provided sterile as are the cited predicate devices.
Performance Specification	Mechanical testing confirmed the FlexitSystem® Knee osteotomy system 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:

a. Static compressive test
b. Dynamic compressive test
c. Torsional properties test per ASTM F543
d. Driving torque test per ASTM F543
e. Pyrogenicity testing per ANSI/AAMI ST72:2011

The results of these tests indicate that the FlexitSystem® Knee osteotomy system is 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 FlexitSystem® Knee osteotomy system 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.