Neosteo
℅ J.D Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S
West Haven, Utah 84401

February 28, 2020

Re: K192447
Trade/Device Name: Superelastic Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: January 28, 2020
Received: January 30, 2020

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,

FOR Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K192447

Device Name

Superelastic Staple

Indications for Use *(Describe)*

The Superelastic Staple are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

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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B. Contact Person

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

August 30, 2019

neosteo
EFFICIENT MOBILITY

510(k) Summary

II. DEVICE IDENTIFICATION

Trade or proprietary name	Superelastic Staple
Common or usual name	Bone Staple
Classification regulation	21 CFR 888.3030
Proposed Regulatory Class	Class II
Panel	87 "Orthopedic"
Product code	JDR
Primary Predicate Device	Biopro Memory Staples® (K061798) from Biopro
Reference Predicate Devices	Memometal Memory Staples (Memoclip – Easy Clip – For Fusion) (K070031) from Memometal ARCAD Compressive Osteosynthesis Staple, EXPRESS Compressive Osteosynthesis Staple (K142111) from Novastep

III. DEVICE DESCRIPTION

The Superelastic Staple consists of staples available in several lengths.

All the implants are made of NiTi alloy.

A. Materials

Superelastic Staple: NiTi alloy per ASTM F2063

510(k) Summary

IV. INTENDED USE

The Superelastic Staple are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

V. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

The Superelastic Staple is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

VI. NON-CLINICAL TEST SUMMARY

The following mechanical tests were performed:

- Static bending test according to ASTM F564 – Annex 4
- Dynamic bending test according to ASTM F564 – Annex 1
- Axial pull-out strength according to ASTM F564 – Annex 2
- Transition temperature according to ASTM F2004
- Corrosion susceptibility testing according to ASTM F2129
- Cytoxicity testing according to ISO 10993-5:2009
- Acute Systemic Toxicity testing according to ISO 10993-11:2006
- Chemical Characterization according to ISO 10993-18:2005

The results of these tests indicate that the Superelastic Staple are equivalent to predicate device.

VII. CLINICAL TEST SUMMARY

No clinical studies were performed.

VIII. CONCLUSIONS NON-CLINICAL AND CLINICAL

NEOSTEO considers the Superelastic Staple 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.