December 4, 2023

Novastep
Manon Dupleichs
Regulatory Affairs Manager
2, Allée Jacques Frimot
35000 Rennes
France

Re: K230724
Trade/Device Name: arcad® 2.0 Duo & Quadro osteosynthesis compressive staples
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: November 6, 2023
Received: November 6, 2023

Dear Manon Dupleichs:

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,

Limin Sun -S

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230724

Device Name

arcad® 2.0 Duo & Quadro osteosynthesis compressive staples

Indications for Use *(Describe)*

arcad® Duo & Quadro osteosynthesis compressive staples are indicated for 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.

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.

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510(k) summary

510(k) summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the **arcad® 2.0 Duo & Quadro osteosynthesis compressive staples**.

SUBMITTER/510(K) HOLDER

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Date Prepared: March 15, 2023

DEVICE NAME

Device name:	arcad®2.0 Duo & Quadro osteosynthesis compressive staples
Device Classification Name:	Staple, Fixation, Bone
Regulation Number:	888.3030
Classification Product Code:	JDR
Device Class:	Class II

PREDICATE DEVICE

Manufacturer:	Novastep® S.A.S
Device name:	ARCAD compressive osteosynthesis staple
Device Classification Name:	Staple, Fixation, Bone
510(k) Number:	K142111
Regulation Number:	888.3030
Classification Product Code:	JDR
Device Class:	Class II

DEVICE DESCRIPTION

arcad® 2.0 Duo & Quadro osteosynthesis compressive staples consists of bone staple implants with two-leg and four-leg configurations with multiple bridge and leg lengths. The implants are manufactured from nickel-titanium alloy (ASTM F2063). The system is provided as a single-use sterile pack comprising of a bone staple implant ready to implant assembled in open legs position on its dedicated disposable insertor forceps and instruments for implantation. The implant is designed to provide compression to facilitate bone fusion with Nitinol pseudoelastic behavior.

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510(k) summary

INTENDED USE/INDICATION FOR USE

The intended use is:

- Osteosynthesis compressive staple

The indication for use is:
arcad®2.0 Duo & Quadro osteosynthesis compressive staples are indicated for foot bone fragments osteotomy fixation and joint arthrodesis.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

Compared to the legally marketed primary predicate **arcad® compressive osteosynthesis staple** (K142111, cleared 19-Dec-2014), the subject **arcad®2.0 Duo & Quadro osteosynthesis compressive staples** has a similar design, intended use (including indication for use), and performance characteristics. The system features the same principles of operation for bone fixation and sterilization method as the predicate system. The subject and predicate are manufactured from the same nitinol material (ASTM F2063) and share similar features such as their legs with teeth. The subject bone staples feature wider bridges while maintaining similar bridge and leg lengths as the predicate devices. The subject system adds sizes with longer bridges, and 4-leg staples when compared to the predicate to further accommodate varying patient anatomy. The system is provided as a single-use sterile pack comprising of a bone staple implant ready to implant assembled in open legs position on its dedicated disposable insertor forceps and instruments for implantation when compared to the predicate.

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

arcad®2.0 Duo & Quadro osteosynthesis compressive staples have undergone functional testing to provide evidence that its non-clinical properties are substantially equivalent to predicate devices already cleared.

Performance testing and engineering analysis demonstrated substantial equivalence to the predicate device in the following (according to FDA guidance for Nitinol products "*Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol*"):

- Static bending, bending fatigue, and pullout strength (per ASTM F564-17 *"Standard Specification and Test Methods for Metallic Bone Staples");*
- Corrosion resistance (per ASTM F2129-19a *"Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices");*
- Thermal analysis by Differential Scanning Calorimetry (per ASTM F2004-17 *"Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis".*

SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Not applicable. Clinical studies were not required for this submission.

CONCLUSIONS

arcad®2.0 Duo & Quadro osteosynthesis compressive staples are substantially equivalent to the predicate device, **arcad® compressive osteosynthesis staple** (K142111, cleared 19-Dec-2014) in terms of intended use, performance, material, manufacturing process and biocompatibility. The design and performance characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices are considered substantially equivalent to the predicate device.