December 14, 2019

Novastep
Gilles Audic
QA/RA Director
Espace Performance III- Batiment P
Saint-Gregoire, 35769 FR

Re: K192356
Trade/Device Name: Airlock Centrolock Osteosynthesis Implant 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
Dated: August 19, 2019
Received: August 29, 2019

Dear Gilles Audic:

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, MPH
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

Indications for Use Statement

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)*
K192356

Device Name
Airlock® Centrolock® osteosynthesis implant system

Indications for Use *(Describe)*
Airlock® Centrolock® osteosynthesis implant systems are single-use devices intended for fixation and stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hands, feet, ankle, fingers and toes.
Examples include:
- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis

The system may be used in adult patients.

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" as required by section 807.92(c)

Submitter	NOVASTEP Espace performance 3 Bâtiment P 35769 SAINT GREGOIRE CEDEX France Phone : + 33 (0)2 99 33 86 50 Fax : + 33 (0)9 70 29 18 95
Contact person	Mister Gilles AUDIC QA / RA Director Cell phone:+33 (0)6 30 93 96 08 e-mail: gilles.audic@novastep-ortho.com
Preparation date	December 13th 2019

Trade name	Airlock® Centrolock® osteosynthesis implant system
Common Name	Plate, Fixation, Bone
Classification Name	Single / Multiple component metallic bone fixation appliances and accessories (21CFR 888.3030, product code HRS)
Regulatory class	II

Legally marketed predicate devices	**Primary predicate device** 510(k) number: K120157 Device name: Mini MaxLock Extreme® Plating System Original applicant: OrthoHelix Surgical Designs, Inc.

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	Reference device 510(k) number: K143523 Device name: Airlock® Osteosynthesis Plate System Original applicant: NOVASTEP. **Other predicate** 510(k) number: K162353 Device name: MICA™ Screw System Original applicant: Wright Medical Technology, Inc..
Description	Airlock® Centrolock® osteosynthesis implant systems are single-use bone fixation devices intended to be permanently implanted. implant system are designed with different shapes and are made of Titanium (Alloy Ti-6Al-4V ELI). The system uses either 2mm cortical screws or 2,5mm locking screws. The drill holes are aligned to make sure there is no risk of conflict between the screws. The implant vary essentially through different curvatures and shapes.
Intended use	Airlock® Centrolock® osteosynthesis implant systems are single-use devices intended for fixation and stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hands, feet, ankle, fingers and toes. Examples include: • Mono or Bi-Cortical osteotomies in the foot or hand • Distal or Proximal metatarsal or metacarpal osteotomies • Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.) • Calcaneus/cuboid arthrodesis • Talar/navicular arthrodesis The system may be used in adult patients.
Comparison of the technological	The new devices Airlock® Centrolock® osteosynthesis implant system implants have similar technological characteristics in terms of design and mechanical characteristics (Static and dynamic bending resistance

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characteristics with the predicate device	(ASTM-F382-17) and thus are believed to be substantially equivalent to the predicate Novastep Airlock® osteosynthesis Plate System. The new devices Airlock® Centrolock® osteosynthesis implant system screws have similar technological characteristics in terms of design and mechanical characteristics (pull-out strength, torsional resistance (ASTMF543-17 sections A1 A3) and thus are believed to be substantially equivalent to the predicate Novastep Airlock® osteosynthesis Plate System.
Performance data	The biocompatibility evaluation for new devices Airlock® Centrolock® osteosynthesis implant systems was conducted in accordance with Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The new devices Airlock® Centrolock® osteosynthesis implant system implants have similar technological characteristics in terms of material (ISO 5832-3 Fourth edition 2016-10-15 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy) and thus are believed to be substantially equivalent to the primary predicate legally marketed device OrthoHelix Surgical Designs Mini MaxLock Extreme® Plating System (K120157), and the reference device marketed Novastep Airlock® osteosynthesis Plate System (K143523). The new devices Airlock® Centrolock® osteosynthesis implant system screws have similar technological characteristics in terms of material (ISO 5832-3 Fourth edition 2016-10-15 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy) and thus are believed to be substantially equivalent to the primary predicate legally marketed device OrthoHelix Surgical Designs Mini MaxLock Extreme® Plating System (K120157), and the reference device marketed Novastep Airlock® osteosynthesis Plate System (K143523).
Indication for use	Airlock® Centrolock® osteosynthesis implant systems are single-use devices intended for fixation and stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hands, feet, ankle, fingers and toes. Examples include: • Mono or Bi-Cortical osteotomies in the foot or hand • Distal or Proximal metatarsal or metacarpal osteotomies • Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

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	• Calcaneus/cuboid arthrodesis • Talar/navicular arthrodesis The system may be used in adult patients.
Clinical studies	Clinical studies were not required for this submission
Animal Study	Animal Study was not required for this submission
Conclusion	The Airlock® Centrolock® osteosynthesis implant systems are substantially equivalent to the primary predicate device OrthoHelix surgical designs Mini MaxLock Extreme® Plating System (K120157), to the reference Novastep Airlock® osteosynthesis plate systems (K143523), and to the other predicate Wright Medical Technology MICA™ Screw System (K162353) in terms of intended use and indications for use. The Airlock® Centrolock® osteosynthesis implant systems are substantially equivalent to the primary predicate device OrthoHelix surgical designs Mini MaxLock Extreme® Plating System (K120157), to the reference Novastep Airlock® osteosynthesis plate systems (K143523) in terms of material, design and function. Any minor differences between these devices do not raise new questions of safety and effectiveness.