March 25, 2026

Novastep SAS
Manon Dupleichs
RA manager
2, Allée Jacques Frimot
Rennes, 35000
France

Re: K260274
Trade/Device Name: Airlock® Ankle Plating 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 29, 2026
Received: January 29, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260274

Please provide the device trade name(s).

Airlock® Ankle Plating System

Please provide your Indications for Use below.

Airlock® Ankle Plating System is indicated for arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints, involving osteotomies of the distal tibia, talus, and calcaneus.
The system can be used in adult patients.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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 **Airlock® Ankle Plating System.**

SUBMITTER/510(K) HOLDER

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Contact Email: manon.dupleichs@enovis.com
Date Prepared: January 29, 2026

DEVICE NAME

Device name:	Airlock® Ankle Plating System
Device Classification Name:	Plate, Fixation, Bone
Regulation Number:	888.3030
Classification Product Code:	HRS
Subsequent Product Codes :	HWC
Device Class:	Class II

PREDICATE DEVICE (PRIMARY)

Manufacturer:	Wright medical technology inc
Device name:	ORTHOLOC 3DI ANKLE FUSION PLATING SYSTEM
Device Classification Name:	Plate, Fixation, Bone
510(k) Number:	K121425
Regulation Number:	888.3030
Classification Product Code:	HRS
Subsequent Product Codes :	HWC
Device Class:	Class II

PREDICATE DEVICE (ADDITIONAL)

Manufacturer:	Paragon 28 (Zimmer Biomet Company)
Device name:	Silverback™ TT/TTC Plating System
Device Classification Name:	Plate, Fixation, Bone
510(k) Number:	K250952
Regulation Number:	888.3030
Classification Product Code:	HRS
Subsequent Product Codes :	HTN, HWC
Device Class:	Class II

PREDICATE DEVICE (ADDITIONAL)

Manufacturer:	Novastep S.A.S.
Device name:	Airlock® osteosynthesis plate systems
Device Classification Name:	Plate, Fixation, Bone
510(k) Number:	K143523
Regulation Number:	888.3030
Classification Product Code:	HRS
Device Class:	Class II

DEVICE DESCRIPTION

Airlock® Ankle Plating System is a range of implantable devices, made of titanium alloy, designed to treat ankle-related indications. Each implant is provided as a single-use sterile device.
The **Airlock® Ankle Plating system** range is constituted by 3 plates variants with holes, available in left and right option for anatomical adaptation. Screws for the fixation and the stabilization of the airlock ankle plates are available in 4 different variants (Locking polyaxial screws Ø4 or Ø4.7 and non-locking screws Ø4 or Ø4.7) and are available in lengths from 14 to 60mm.

INTENDED USE/INDICATION FOR USE

The intended use is:

- **Airlock® Ankle Plating System** intended for the fixation of arthrodesis of the ankle.

The indication for use is:
Airlock® Ankle Plating System is indicated for arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints, involving osteotomies of the distal tibia, talus, and calcaneus.
The system can be used in adult patients.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATES DEVICES

Airlock® Ankle Plating System is substantially equivalent to the predicate devices**, ORTHOLOC 3DI ANKLE FUSION PLATING SYSTEM** (primary predicate, K121425), **Silverback™ TT/TTC Plating System** (additional predicate, K250952) and **Airlock® osteosynthesis plate systems** (additional predicate, K143523). The subject device has similar indications for use, and technological characteristics as the predicate devices.

The subject device features the same principles of operation for bone fixation. It is manufactured from the same TA6V alloy (ASTM F136) and shares similar features such as polyaxial locking, anatomical design and plate positioning. The subject device features short talar neck for patient anatomical adaptation, visual indications on the plate to facilitate positioning on the patient and the insertion of the dedicated tibio-talar screw. Each single device is provided single-use sterile pack and ready to use for the hospitals/clinics.

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

Performance tests have been done according to the FDA guidance's "*Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway*" (April 11, 2022) and "*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*" (November 22, 2024):

- Static Four-Point Bending on plates (per ASTM F382-24),
- Torsional Strength, Driving Torque and Axial Pullout Strength on screws (per ASTM F543-23),
- Sterilization validation according to IDO 11137-1, 2 and 3 and ISO 11607-1 and 2,
- Biocompatibility of the device assessed using ISO 10993-1:2018.

SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

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

CONCLUSIONS

Airlock® Ankle Plating System is substantially equivalent to the predicate devices**, ORTHOLOC 3DI ANKLE FUSION PLATING SYSTEM** (primary predicate, K121425) and **Silverback™ TT/TTC Plating System** (additional predicate, K250952) and **Airlock® osteosynthesis plate systems** (additional predicate, K143523) .
Airlock® Ankle Plating System is has also demonstrated its safety and performance according to the FDA guidance's "*Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway*" and "*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*".