DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2015

NOVASTEP
Mr. Gilles Audic, QA/RA Director
Espace performance Alphasis
Batiment Cl-C2
35769 SAINT GREGOIRE
France

Re: K151277
Trade/Device Name: Airlock® osteosynthesis plate 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: May 21, 2015
Received: May 26, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section

4: 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151277

Device Name
Airlock® osteosynthesis plate systems

Indications for Use *(Describe)*
Airlock® osteosynthesis plate systems are indicated for fixation and stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system may be used in both adult and pediatric 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

novastep®

"510(k) Summary" as required by section 807.92(c)

Submitter	NOVASTEP Espace performance Alphasis Bâtiment C1-C2 35769 SAINT GREGOIRE 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	May 12th 2015

Trade name	Airlock® osteosynthesis plate 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	510(k) number: K083447 Device name: Anchorage® Bone Plate System Original applicant: MEMOMETAL TECHNOLOGIES. This predicate has not been subject to a design-related recall.
Description	Airlock® osteosynthesis plate systems are are single-use bone fixation devices intended to be permanently implanted. Plates are designed with different shapes and are made of Titanium (Alloy Ti-6Al-4V ELI). The system uses either 3mm or 3,5mm locking and non-locking screws.

	The drill hole are aligned to make sure there is no risk of conflict between the screws. The plates vary essentially through different curvatures, lengths, number of holes and shape.
Intended use	Airlock® osteosynthesis plate systems are single use devices intended for fixation and stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system may be used in both adult and pediatric patients.
Comparison of the technological characteristics with the predicate device	The new devices Airlock® osteosynthesis plate systems plates have similar technological characteristics in terms of material (ISO5832-3 Implants for surgery – Metallic material – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy) and mechanical characteristics (ASTM F382-99 Standard Specification and Test Methods for Metallic Bone plates) and thus are believed to be substantially equivalent to the predicate MEMOMETAL Anchorage® Bone Plate System plates (K083447). The new devices Airlock® osteosynthesis plate systems screws have similar technological characteristics in terms of material (ISO5832-3 Implants for surgery – Metallic material – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy) and mechanical characteristics (ASTM F543-13 Standard Specification and Test Methods for Metallic Bone screws Part A1, A2 & A3) and thus are believed to be substantially equivalent to the predicate MEMOMETAL Anchorage® Bone Plate System screws (K083447).
Performance data	The biocompatibility evaluation for new devices Airlock® osteosynthesis plate 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® osteosynthesis plate systems have similar technological characteristics in terms of design and mechanical characteristics and thus are believed to be substantially equivalent to the predicate MEMOMETAL Anchorage® Bone Plate System (K083447).
Indication for use	The Airlock® osteosynthesis plate systems are single use devices indicated for fixation and stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system may be used in both adult and pediatric patients.
Clinical studies	Clinical studies was not required for this submission

novastep - Siège Social / Service Client
Espace Performance Alphasis - Bâtiment C1-C2 - 35769 SAINT-GRÉGOIRE Cedex - FRANCE
Tél. +33 (0)2 99 33 86 50 - Fax : +33 (0)2 30 96 35 61
Code A.P.E. : 3250A - N° SIRET : 752 292 797 00020 - N° TVA Intracommunautaire FR 64 752 292 797

Animal Study	Animal Study was not required for this submission
Conclusion	The Airlock® osteosynthesis plate systems are substantially equivalent to their predicate devices MEMOMETAL Anchorage® Bone Plate System (K083447), in terms of intended use and indications for use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

novastep - Siège Social / Service Client
Espace Performance Alphasis - Bâtiment C1-C2 - 35769 SAINT-GRÉGOIRE Cedex - FRANCE
Tél. +33 (0)2 99 33 86 50 - Fax : +33 (0)2 30 96 35 61
Code A.P.E. : 3250A - N° SIRET : 752 292 797 00020 - N° TVA Intracommunautaire FR 64 752 292 797