August 30, 2023

Novastep
Gilles Audic
QA/RA director
2, allée Jacques Frimot
Rennes, 350000
France

Re: K223468
Trade/Device Name: Nexis® compressive screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 1, 2023
Received: August 1, 2023

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 -S

Shumaya Ali, M.P.H.
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

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.

510(k) Number *(if known)*
K223468

Device Name
Nexis® compressive screws

Indications for Use *(Describe)*
Nexis® compressive screws system is a single use device indicated for the fixation, correction or stabilization of bones and bone fragments of the foot and ankle in adult patients. The system is indicated for:

Ø5.0mm compressive screw:
- Os Calcis and talar fractures
- Calcaneus osteotomies
- Arthrodesis of the tarsals

Ø7.0mm compressive screw:
- Ankle arthrodesis
- Calcaneus osteotomies

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.

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 Nexis® compressive screws.

SUBMITTER/510(K) HOLDER

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Date Prepared: November 17, 2022

DEVICE NAME

Device name:	Nexis® compressive screws
Device Classification Name:	Screw, fixation, bone
Regulation Number:	888.3040
Classification Product Code:	HWC
Device Class:	Class II

PREDICATE DEVICE

Primary Predicate

Manufacturer:	Stryker Trauma AG
Device name:	FIXOS SCREW SYSTEM
Device Classification Name:	Screw, fixation, bone
510(k) Number:	K133451
Regulation Number:	888.3040
Classification Product Code:	HWC
Device Class:	Class II

Additional Predicate

Manufacturer:	WRIGHT MEDICAL TECHNOLOGY, INC.
Device name:	DARCO HEADLESS COMPRESSION SCREW
Device Classification Name:	Screw, fixation, bone
510(k) Number:	K080850
Regulation Number:	888.3040
Classification Product Code:	HWC
Device Class:	Class II

Additional Predicate

Manufacturer:	Novastep® S.A.S
Device name:	Nexis osteosynthesis compressive screws
Device Classification Name:	Screw, fixation, bone
510(k) Number:	K143229
Regulation Number:	888.3040
Classification Product Code:	HWC
Device Class:	Class II

DEVICE DESCRIPTION

Nexis® is a range of osteosynthesis compressive single use screws, made of titanium alloy, designed to address foot and ankle indications. These devices are designed for stable fixation and have quick insertion features.

They are implantable medical devices intended to be used in orthopedics for foot and ankle surgery.
The device is sold sterile. The shelf life is 5 years.

INTENDED USE/INDICATION FOR USE

The intended use is:

- Osteosynthesis compressive screw

The indication for use is:

- Nexis® compressive screws system is a single use device indicated for the fixation, correction or stabilization of bones and bone fragments of the foot and ankle in adult patients. The system is indicated for:

  Ø5.0mm compressive screw:
  - Os Calcis and talar fractures
  - Calcaneus osteotomies
  - Arthrodesis of the tarsals

  Ø7.0mm compressive screw:
  - Ankle arthrodesis
  - Calcaneus osteotomies

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

Novastep® S.A.S. demonstrated that **Nexis® compressive screws** are substantially equivalent to the predicate devices, **FIXOS SCREW SYSTEM** (primary predicate device, K133451, cleared 28-Feb-2014) in term of intended use (including indication for use) and performance, **DARCO HEADLESS COMPRESSION SCREW** (additional predicate device, K080850, cleared 04-Oct-2008) in term of design characteristics and **Nexis osteosynthesis compressive screws** (secondary predicate device, K143229, cleared 02-Jun-2015) in term of the safety of the device, with equivalence on raw material, manufacturing process and biocompatibility. The subject device indications for use, technological characteristics and overall design are substantially equivalent to those of the predicate devices. Any minor differences in design and performance do not raise any questions of safety or effectiveness.

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

Nexis® compressive screws have undergone functional testing to provide evidence that its non-clinical properties are substantially equivalent to predicate devices already cleared.
Functional tests have been done according to the FDA Guidance "orthopedic non-Spinal metallic bone screw and washers – Performance Criteria for safety and Performance based pathway" issued December 11, 2021:

- Torsion resistance of the screws must be assessed to prevent screw breakage during insertion or removal.
  Test performed according to ASTM F543-17 and evaluated against a predicate device.
- Strength needed to insert and remove screws must be evaluated to avoid failure of the screw during insertion or the removal.
  Tests performed according to ASTM F543-17.
- Axial pull out resistance of the screws must be assessed to valid a suitable anchorage when subjected to tensile forces, poor bone quality or osteoporotic bone.
  Assessed using the equation described by Chapman et al., 1996.
- Sterilization and reprocessing validations to demonstrate the cleanliness and the sterility of, and the ability to clean and sterilize to a sterility assurance level of 10^{-6}, the device and device-specific instruments.
  Tests performed according to ISO 11137-1, ISO 11607-1 and ISO 11607-2.

- 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

Nexis® compressive screws are substantially equivalent to the predicate devices, **FIXOS SCREW SYSTEM** (K133451, cleared 28-Feb-2014) in term of intended use and performance, **DARCO HEADLESS COMPRESSION SCREW** (K080850, cleared 04-Oct-2008) in terms design and function and **Nexis osteosynthesis compressive screws** (K143229, cleared 02-Jun-2015) in terms of material, manufacturing process and biocompatibility. Any minor differences between these devices do not raise new questions of safety and effectiveness.