October 19, 2022

Neos Surgery SL
℅ Cherita James
Regulatory Consultant
M Squared Associates, Inc.
127 West 30th Street, 9th Floor
New York, New York 10001

Re: K221795
Trade/Device Name: STERN FIX Sternal Stabilization System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: July 21, 2022
Received: July 22, 2022

Dear Cherita James:

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,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K221795

Device Name
STERN FIX Sternal Stabilization System

Indications for Use *(Describe)*
The STERN FIX Sternal Stabilization System is intended for closure and stabilization of the sternum following sternotomy, through the intercostal spaces, in order to promote its fusion.

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

The following information is provided as required by 21 CFR § 807.87 for the STERN FIX Sternal Stabilization System Traditional 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Neos Surgery S.L.
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Date of Submission: June 16, 2022

Proprietary Name: STERN FIX Sternal Stabilization System

Common Name: Cerclage, fixation

Regulatory Class: II

Regulation: 888.3010 Bone fixation cerclage

Product Codes: JDQ

Primary Predicate Device(s): STERN FIX Sternal Stabilization System – K211613

Device Description

The STERN FIX is a long-term implantable postoperative sternal stabilization system that closes and stabilizes the sternum after a sternotomy. The STERN FIX is a clamping device consisting of two parts, male and female, which match telescopically with one another to form the sternal stabilization system. Both male and female parts have a curved arm that catches one of the two

halves of the sternum laterally and approximates them until the sternum is securely fixed. Five sizes of the STERN FIX are available for use with different sternum thicknesses. The STERN FIX can be cut and removed for emergent, and long-term, re-entry through the sternum. The predicate device was originally made of PEEK-OPTIMA™. This 510(k) introduces a new variant of the product made of carbon-fiber reinforced (CFR) PEEK-OPTIMA™. This new variant also presents some minor geometry changes with respect to the predicate device, to adapt the product to the new material.

Indications for Use

The STERN FIX *Sternal Stabilization System* is intended for closure and stabilization of the sternum following sternotomy, through the intercostal spaces, in order to promote its fusion.

Technological characteristics, comparison to predicate device

Device	**STERN FIX (Current product, cleared in K211613)**	**STERN FIX (Modified)**
Company	NEOS Surgery S.L.	NEOS Surgery S.L.
510(k) No.	K211613	Present document
Product Code	JDQ- Cerclage, Fixation	Same
Indications for Use	The STERN FIX *Sternal Stabilization System* is intended for closure and stabilization of the sternum following sternotomy, through the intercostal spaces, in order to promote its fusion.	Same
Method of Fixation to Sternum	Peristernally, through the intercostal spaces. Generally, 5 STERN FIX devices are recommended per median sternotomy closure, but they can be used in combination with other sternal closure systems such as wires or plates.	Same

Device	STERN FIX (Current product, cleared in K211613)	STERN FIX (Modified)
Device Design	The STERN FIX device consists of two parts, male and female, which match telescopically with one another to form the fixation system. Both male and female parts have a curved arm that catches laterally one of the two halves of the sternum and approximates them until the sternum is securely fixed. Both parts present a set of teeth that, together, form a ratchet mechanism that allows their movement in the closing direction and, at the same time, impedes their backward movement. The tightening of both implant parts (male and female) is carried out using an application tool. The STERN FIX can be cut and removed for emergent, and long-term, re-entry through the sternum.	Same
Range of sternum thicknesses and widths covered	**Thickness**: From 9.5 to 17 mm **Width**: From 17 to 38 mm	Same
Accessories	Four instruments are used to implant the device: • A depth gauge (SCI0000) to select the appropriate STERN FIX size. • Forceps (SCI0501) to tighten and adjust the STERN FIX during its implantation. • A cutter (SCI0200) to cut the excess segment of the male part or cut the device safely in case of need of device removal. • A retractor (SCI0300) to ease the introduction of the STERN FIX in the intercostal spaces.	Besides the four instruments already included in the cleared version of the product (SCI0000, SCI0501, SCI0200, SCI0300), a new alternate cutter (SCI0700) is added. This instrument may be used as an alternative to SCI0200, if preferred by the user, to cut the excess segment of the male part.
Material Composition	PEEK-OPTIMA™ LT3, according to ASTM F2026	PEEK-OPTIMA™ LT1CA30, according to ASTM F3333-20
Sizes	Five sizes that allow implantation in sternal bones of all thicknesses considered (from 9.5 mm to 17 mm). Its length can be adjusted to fit each sternal bone width by cutting the excess segment of the male part.	Same
Implant life	Long-term implant	Same
Sterility	Provided sterile. E-beam	Same

Technological Characteristics and Substantial Equivalence

The changes proposed for the modified STERN FIX do not change the indications for use of the original product, nor its contraindications, potential side effects or adverse events. The group of users and the use environment also remain unchanged. The material change does not imply any

new or increased biocompatibility concerns, based on the risk assessment performed. The changes on the geometry do not modify the critical dimensions of the product, nor do they imply a modification of the design requirements or the final product specifications. Similarly, the sternum thickness and width range for which the device can be used, as well as the implantation method, remain the same. Finally, the addition of a new accessory (SCI0700) does not affect the directions of use nor the implantation method of the device.

In summary, the modified STERN FIX is substantially equivalent to its predicate device with regards to indications for use, technological characteristics, principles of operation and performance.

Performance testing

Performance testing was conducted to characterize the capacity of the modified STERN FIX, as a sternal stabilization system, to withstand the forces that act upon the sternum and the whole fixation system once the products have been implanted. The results of the tests confirm the adequate performance of the device, and that it is able to achieve its intended use.

Performance testing has demonstrated that the technological characteristics of the modified STERN FIX do not raise any new safety or effectiveness issues and that it will perform as intended in the clinical setting. A summary of the tests performed follows:

Test	Conclusions
Functional testing	
Breaking strength	All tested samples meet the specifications. Functionality of the devices is demonstrated.
Fatigue test	All tested samples meet the specifications. Functionality of the devices is demonstrated.
Biomechanical testing	
Breaking strength	All tested samples meet the specifications. The STERN FIX system has an adequate biomechanical behavior when subject to relevant efforts.
Lateral distraction test	All tested samples meet the specifications. The STERN FIX system has an adequate biomechanical behavior when subject to relevant efforts.

Cadaver testing	Correct devices implantation is verified in a simulated real-life situation. The devices show adequate performance and safety.

Conformance to Standards

The STERN FIX *Sternal Stabilization System* is in conformance to the following recognized consensus standards:

Standard	Recognition Number
ISO 14971 Third edition 2019-012: Medical devices - Application of risk management to medical devices	5-125
ISO 14630 Fourth edition 2012-12-01: Non-active surgical implants -- General requirements	11-254
ISO 11607-1 Second edition 2019-02: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530
ISO 11607-2 Second edition 2019-02: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	14-531
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION: Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-129
ISO 11137-1 First edition 2006-04-15: Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]	14-528
ISO 11137-2 Third edition 2013-06-01: Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	14-409
ISO 11737-1 Third edition 2018-01: Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product	14-514
ISO 11737-2 Third edition 2019-12: Sterilization of medical devices -	14-540

Standard	Recognition Number
Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	
ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
ISO 10993-5 Third edition 2009-06-01: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2-245
ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	5-134
ISO 17665-1 First edition 2006-08-15: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	14-333
ISO 17664 Second edition 2017-10: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	14-515
ASTM F2026-17: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	8-475
ASTM F2503-20: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	8-528

Discussion of clinical testing

No clinical testing was performed to support this submission.

Conclusion

Based on the comparison of the intended use (based on the indications for use), product technical characteristics, principles of operation and performance, the modified STERN FIX has demonstrated substantial equivalence to the previously cleared STERN FIX product. The differences do not raise new issues of safety or effectiveness, based on the risk assessment

performed and on the results of the verification / validation activities that have been conducted.