CircumFix Solutions, Inc.
% Danielle Besal
Principal Consultant
MRC Global
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

January 30, 2024

Re: K232986
Trade/Device Name: VariTrax Sternal CircumFixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS
Dated: December 28, 2023
Received: December 28, 2023

Dear Danielle Besal:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.01.30 08:39:43 -05'00'

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)*
K232986

Device Name
VariTrax Sternal CircumFixation System

Indications for Use *(Describe)*
The VariTrax Sternal CircumFixation system is indicated for primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote 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
VariTrax Sternal CircumFixation System
K232986
January 25, 2024

Company: CircumFix Solutions, Inc.
475 East South St, Suite 102
Collierville, TN 38017

Primary Contact: Danielle Besal
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901.827.8670
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Company Contact: Ken Richardson
Chief Commercial Officer | CircumFix Solutions
901.504.0813
kwrichardson@circumfixsolutions.com

Trade Name: VariTrax Sternal CircumFixation System
Common Name: Sternal fixation system
Classification: Class II
Regulation Number: 21 CFR 888.3010 (Primary), Bone fixation cerclage
21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Product Code: JDQ (Primary), HRS
Predicate Devices: K110789 Synthes Sternal ZipFix System (primary) K946173
Ethicon Stainless Steel Suture Wire (additional) K151983
KLS Martin LSS Plating System (additional)

Device Description:
The VariTrax Sternal CircumFixation System consists of polyetheretherketone (PEEK) locking bands with a detachable stainless-steel needle and a PEEK buttress plate. They are single-use devices provided in a sterile kit. The VariTrax bands are placed in peristernal fashion through the intercostal space with the help of the detachable needle. Once inserted, the needle is removed and the VariTrax implants are attached and locked to the VariTrax buttress plate, then tightened and secured in place to provide stable fixation of the sternum.

Indications for Use:
The VariTrax Sternal CircumFixation system is indicated for primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Substantial Equivalence:
The VariTrax Sternal CircumFixation System is substantially equivalent to the predicate devices (K110789, K946173, K151983). The subject and predicate devices are identical in intended use and materials and equivalent in technological characteristics. Testing has demonstrated that performance of the subject devices is equivalent to that of the predicates and, thus, the differences in geometry versus the predicates do not raise different questions of safety and effectiveness.

Performance Testing:
Biocompatibility testing per ISO 10993-1 and performance testing (lateral distraction, longitudinal shear, static tensile band, four-point bend, and needle pull out) was conducted on the subject devices and results demonstrated substantial equivalence to the predicates.

Conclusion:
The VariTrax Sternal CircumFixation System is considered substantially equivalent to the predicate Synthes Sternal ZipFix System (K110789), Ethicon Stainless Steel Suture Wire (K946173), and KLS Martin LSS Plating System (K151983).