January 26, 2022

Fusion Innovations, LLC
℅ Katelyn Jessup
Regulatory & Quality Specialist
Kapstone Medical, LLC
520 Elliot Street
Charlotte, North Carolina 28202

Re: K202914
Trade/Device Name: SternaFuse Fixation System
Regulation Number: 21 CFR 888.3030, 888.3040
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 20, 2022
Received: January 21, 2022

Dear Katelyn Jessup:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202914

Device Name
SternaFuse® Fixation System

Indications for Use *(Describe)*
The SternaFuse® Fixation System is indicated for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy, sternal fractures, and sternal reconstructive surgical procedures, to promote fusion. The device is for prescription use only.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

1. Date of Preparation:

January 26, 2022

2. Applicant

Fusion Innovations, LLC
341 N. Maitland Ave. Ste. 270
Maitland, FL 32751 USA

3. Submitter/Contact Person

Katelyn Jessup
Regulatory and Quality Specialist
Kapstone Medical LLC
520 Elliot St.
Charlotte, NC 28202
(856) 577-3432

4. Device Name

Trade Name: SternaFuse® Fixation System
Common Name: Plate, Fixation, Bone (primary), and Screw Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (primary), Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number: 888.3030 (primary), 888.3040
Product Code: HRS (primary), HWC
Classification: Class II
Panel: Orthopedic

5. Predicate Devices

Biomet Microfixation Sternal Closure System (K111908) – Primary
Ethi-pack Surgical Stainless Steel Suture (K931271) – Reference

6. Indications for Use (Intended Purpose and Conditions of Use):

The SternaFuse® Fixation System is indicated for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy, sternal fractures, and sternal reconstructive surgical procedures, to promote fusion. The device is for prescription use only.

7. Device Description

The SternaFuse® Fixation System implants are composed of 316 LVM implant quality stainless steel plates, links, and screws intended to stabilize and fixate fractures of the anterior chest wall. The components include various sizes to facilitate customization according to the requirements of the anterior chest wall repair. Self-drilling locking screws come in two diameters, 3.0mm and 3.3mm, and lengths of 10mm, 13mm, and 16mm. Multiple plates may be used in one anterior chest wall repair. Variable Assemblies can be configured, and the Links angled for optimum fixation. Implants are designed with centralized saddles to aid in intra-operative contouring, to facilitate cutting during postoperative emergent re-entry, and to provide a location for stainless steel wire.

The implants are individually packaged and sterilized, allowing the surgeon to customize the desired implants for the specific needs of the patient. All implants are provided sterile with a five-year shelf-life. The implants should never be reused under any circumstance.

8. Comparison of Technological Characteristics with the Predicate Devices

As was established in this submission, the subject device SternaFuse® Fixation System is substantially equivalent to the predicate device, cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas including design, intended use, material composition, function, and sterility.

9. Performance Data

There are no clinical data generated and held by the manufacturer, i.e., no pre-marketing or post-market clinical studies or animal studies have been performed. The following information is provided in support of substantial equivalence.

9.1 Biocompatibility

The SternaFuse® Fixation System implants are classified as an implant device with tissue/bone contact and permanent contact. Therefore, according to ISO 10993-1, the biological evaluation was assessed for potential effects. The SternaFuse® Fixation System devices are manufactured from 316LVM Stainless Steel conforming to ASTM standard F138. The evaluation was based on a risk assessment of the device considering materials, manufacturing process, and finished device testing. The results show that implants made of 316LVM Stainless Steel have a high demonstratable biological safety. No concerns arose that would preclude clinical use of the SternaFuse® Fixation System. The requirements of the ISO 10993 standard are fulfilled.

9.2 Pyrogenicity / Endotoxin Testing

The bacterial endotoxin test was performed utilizing worst case subject implants to verify that the subject implants meet the acceptance criteria of ≤ 20 EU/device. Testing was successfully performed, and it was confirmed that the SternaFuse® Fixation System meets the acceptance criteria of ≤ 20 EU/device according to USP, General Chapter <85>, Bacterial Endotoxins Test, and EP Ch 2.6.14 Bacterial Endotoxins as recommended in ISO 10993-11:2009 Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity. Endotoxin testing will be conducted on every lot.

9.3 Packaging/Sterility

The SternaFuse® Fixation System implants are supplied sterile to the end user, packaged in a container within a pouch. The pouch serves as the sterile barrier and is intended to maintain sterility of the packaged medical device. The pouch has undergone validation, in accordance with ISO 11607-1, to demonstrate the sterile barrier ability after gamma irradiation and after the claimed shelf-life. A transport simulation was performed according to ASTM D4169. Sterilization validation was performed according to ISO 11137.

The SternaFuse® Fixation System also includes single-use, disposable surgical instrumentation to assist with implantation. Driver bits are provided sterile, packaged in the same container and pouch described above.

9.4 Mechanical Testing

The following testing was performed to demonstrate equivalence:

- Static Tension Testing
- Dynamic Tension Testing

- Screw Pullout Testing per ASTM F543
- Driving Torque Testing per ASTM F543
- Torsion Testing per ASTM F543

9.5 MR Safety Testing

The SternaFuse® Fixation System implants are manufactured using non-ferromagnetic 316 Stainless Steel. The implants have not been evaluated for safety, heating, migration, or compatibility in the MR environment. The SternaFuse® Fixation System has not been tested for heating, migration, or image artefact in the MR environment. The safety of the SternaFuse® Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

10. Conclusion

The SternaFuse® Fixation System and the predicate device Biomet Microfixation Sternal Closure System (K111908) have the same “Indications for Use,” and are available by prescription only. Compared to the reference device, the SternaFuse® Fixation System is manufactured from the same material and biocompatible. Any technical differences, which were identified, do not result in new questions of safety or effectiveness.

Through assessment of technological characteristics, indications for use and performance data, it can be concluded that SternaFuse® Fixation System is both a safe and effective device and is substantially equivalent to the Biomet Microfixation Sternal Closure System and Ethi-pack Surgical Stainless Steel Suture.