November 19, 2025

Fusion Innovations, LLC
% Sarah Robbins
Quality Consultant
Rook Quality Systems
1155 Mount Vernon Hwy
Suite 800
Dunwoody, Georgia 30338

Re: K252661
Trade/Device Name: SternaFuse Ti Fixation 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, HWC
Dated: May 13, 2025
Received: August 22, 2025

Dear Sarah Robbins:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252661

Please provide the device trade name(s).

SternaFuse Ti Fixation System

Please provide your Indications for Use below.

The SternaFuse Ti Fixation System is indicated for use in the stabilization and fixation of fractures of the anterior chest wall or sternum, including sternal fixation following sternotomy, sternal fractures, and sternal reconstructive surgical procedures to promote fusion. The system is intended for use in patients with normal and/or poor bone quality. The device is for prescription use only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252661

510(k) Summary

Prepared on: 2025-08-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fusion Innovations, LLC
Applicant Address	341 N. Maitland Ave #270 Maitland FL 32751 United States
Applicant Contact Telephone	636-399-5446
Applicant Contact	Mr. Adam Cowick
Applicant Contact Email	a.cowick@fusioninnovations.com
Correspondent Name	Rook Quality Systems
Correspondent Address	1155 Mount Vernon Hwy Suite 800 Dunwoody GA 30338 United States
Correspondent Contact Telephone	803-338-6041
Correspondent Contact	Ms. Sarah Robbins
Correspondent Contact Email	sarah.robbins@rookqs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SternaFuse Ti Fixation System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202914	SternaFuse Fixation System	HRS
K111908	Biomet Microfixation Sternal Closure System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The SternaFuse Ti Fixation System implants are manufactured from titanium alloy (Ti6AL-4V ELI) Per ASTM F136 implant quality titanium plates, 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 3.5mm diameter, and lengths of 10mm, 12mm,14mm,16mm,18mm and 20mm. Multiple plates may be used in one anterior chest wall repair.
All implants are provided non-sterile. The implants should never be reused under any circumstance.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SternaFuse Ti Fixation System is indicated for use in the stabilization and fixation of fractures of the anterior chest wall or sternum, including sternal fixation following sternotomy, sternal fractures, and sternal reconstructive surgical procedures to promote fusion. The system is intended for use in patients with normal and/or poor bone quality. The device is for prescription use only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Fusion Innovations SternaFuse Ti Fixation System is substantially equivalent to the predicate devices, the SternaFuse Fixation System Sternal Closure System (K202904), and the Biomet Microfixation Sternal Closure System (K111908).
The subject device shares the same intended use as these devices, for sternal closure following median sternotomy, and is available by prescription only. It has similar indications, application methods, and fixation principles. The SternaFuse Ti Fixation System is made from titanium; the same material used in the Biomet Microfixation system. Although there are minor technological differences between the subject device and the predicate devices, these differences do not raise new questions of safety or effectiveness. Bench testing, including evaluations of static and dynamic tension, pullout strength, driving torque, and torsional resistance, demonstrated that the subject device performs equal to or better than the predicate and reference devices. Therefore, the SternaFuse Ti Fixation System is concluded to be safe and effective and is substantially equivalent to the predicate and reference devices.

Technological Comparison

21 CFR 807.92(a)(6)

While the SternaFuse Ti Fixation System has minor technical differences compared to the predicates (K202904 and K111908), these differences have been thoroughly evaluated and do not raise new questions of safety or effectiveness. Differences may include variations in implant geometry, screw dimensions, or instrument design; however, these were specifically engineered to optimize ease of use, implant stability, and surgical workflow. All materials used are biocompatible, and the titanium construction is consistent with the material used in K111908. Comprehensive bench testing, including static and dynamic tension, pullout strength, driving torque, and torsional resistance, demonstrated that the performance of the SternaFuse Ti Fixation System meets or exceeds that of the predicate devices. These technical modifications do not affect the device's intended use or clinical function and are fully supported by performance data. Therefore, the technical differences are justified and do not impact the overall safety or effectiveness of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

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

No clinical testing was required to support substantial equivalence to the predicate device.

Through comparison of mechanical test data to predicate devices with similar intentions, the SternaFuse Ti Fixation System shows itself to be mechanically similar or better in its mechanical stability to the predicate device in its ability to maintain closure of the chest wall until fusion can occur.
The static and dynamic tension test results of the SternaFuse Ti Fixation System devices are statistically equivalent to or greater than that of the predicate devices.
In conclusion, the acceptance criteria have been met, and the mechanical data shows the SternaFuse Ti Fixation System to be superior in resisting lateral forces. The SternaFuse Ti Fixation System performed superior or demonstrated substantial equivalence to the predicate devices.
All biomechanical performance testing for static axial and dynamic axial tension, show that the SternaFuse Ti Fixation System is equal to or greater than the predicate devices. It can be concluded the SternaFuse Ti Fixation System is as safe and effective device and is substantially equivalent to the predicate devices.