April 20, 2024

SAIL Fusion, LLC
Benjamin Arnold
Official Applicant
2010 Jimmy Durante Blvd
Suite 200
Del Mar, California 92014

Re: K232149
Trade/Device Name: BowTie™ SI Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: March 13, 2024
Received: March 21, 2024

Dear Benjamin Arnold:

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,

Colin O'neill -S

FDA

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)*
K232149

Device Name
BowTie™ SI Joint Fusion System

Indications for Use *(Describe)*
The BowTie™ SI Joint Fusion System is indicated for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the BowTie SI Fusion System is implanted, both the Iliac and Transfix Screw components must be used.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

SUBMITTER:

Company Name: SAIL Fusion, LLC
Address: 2010 Jimmy Durante Blvd, Suite 200
Del Mar, CA 92014
Telephone: 607.351.6131

CONTACT PERSON: Benjamin Arnold

DATE PREPARED: 7/18/2023

TRADE NAME: BowTie™ SI Joint Fusion System

COMMON NAME: Sacroiliac Joint Fixation Device

CLASSIFICATION NAME: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
REGULATORY CLASS: II
PRODUCT CODE: OUR

SUBSTANTIAL EQUIVALENCE:
The BowTie™ SI Joint Fusion System is substantially equivalent to the primary predicate device in all facets including function, design, performance, material, and intended use.

Primary Predicate Device: Aurora Spine, Inc. SILO TFX MIS Sacroiliac Joint Fixation System (K221047)

DEVICE DESCRIPTION:
The BowTie™ SI Joint Fusion System is intended to provide stabilization of the sacroiliac joint until fusion occurs. The device consists of an implant and a set of ancillary instruments. The implant is comprised of an interarticular component, an iliac screw, and a transfix screw. All implant components are titanium and available in various sizes to accommodate varying patient anatomy. The implant components are provided gamma sterilized and individually packaged. The ancillary instruments are provided non-sterile and will be sterilized by the end user.

MATERIALS:
The BowTie™ SI Joint Fusion System interarticular component is additively manufactured from Ti-6Al-4V ELI per ASTM F3001. The Posterior Sacroiliac Joint Fusion Device screws are machined from Ti-6Al-4V ELI per ASTM F136.

INDICATIONS FOR USE:
The BowTie™ SI Joint Fusion System is indicated for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the Bowtie SI Fusion System is implanted, both the Iliac and Transfix Screw components must be used.

TECHNOLOGICAL CHARACTERISTICS:
The BowTie™ SI Joint Fusion System implant components are made from similar materials and have equivalent design philosophy, sizing, configurations, fixation methods, sterilization and packaging, and surgical approach to the predicate device. Any differences between the Posterior Sacroiliac Joint Fusion Device and the predicate are considered minor and do not raise questions concerning safety or effectiveness.

PERFORMANCE TESTING:
The following bench testing was performed on the BowTie™ SI Joint Fusion System**:**

- Cadaveric Biomechanical Evaluation of SAIL Implant Construct
- Implant Static Torsion per ASTM F3574
- Fatigue Vertical Shear Testing per ASTM F3574
- Porous Coating Characterization per ASTM F1854
- Implant Fatigue Torsion Testing per ASTM F3574
- Static Vertical Shear Testing per ASTM F3574
- Bone Screw Mechanical Testing – Torsion Strength per ASTM F543
- Bone Screw Mechanical Testing – Insertion Torque per ASTM F543
- Bone Screw Mechanical Testing – Pull-Out per ASTM F543
- Bone Screw Mechanical Testing – Static Cantilever Bending Testing per ASTM F2193
- Bone Screw Mechanical Testing – Fatigue Cantilever Bending Testing per ASTM F2193

In summary, rationales and mechanical testing of the BowTie™ SI Joint Fusion System indicated there are no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSIONS:
The BowTie™ SI Joint Fusion System is substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices.