June 6, 2025

SI-TECHNOLOGY, LLC
℅ Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy
Woodstock, Georgia 30188

Re: K251525
Trade/Device Name: SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac 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: May 19, 2025
Received: May 19, 2025

Dear Justin Gracyalny:

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,

STEPHANIE SMITH -S

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

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.	K251525

Please provide the device trade name(s).

SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System

Please provide your Indications for Use below.

The SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

The SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

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) Summary:
SI-TECHNOLOGY® SI-DESIS® X™
Sacroiliac Joint Fusion System

Date	May 16, 2025
Sponsor	SI-TECHNOLOGY, LLC 320 East Vine Drive, Suite 217 Fort Collins, Colorado, USA 80524
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE 7828 Hickory Flat Highway Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System
Common Name	Sacroiliac Joint Fixation
Code–Classification	OUR 21 CFR 888.3040 : Class II
Primary Predicate	SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System (K241813)
Device Description	The SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System consists of an X shaped implant designed to assist in the healing of sacroiliac (SI) joints for fusion by providing fixation of the sacroiliac joint. The implant is not intended to replace normal body structures. The implant is offered in five variations with one size per variation. The implant is manufactured from titanium alloy per ASTM F136. The SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System was designed as a less invasive alternative to traditional open posterior surgical SI joint fusion. The titanium implant consists of a sacrum engaging side and an ilium engaging side connected by a bridge. During the procedure, bone graft material is placed in the window of the implant to facilitate stabilization. The implant is intended for single-use only. Implants are provided clean and non-sterile and designed for routine steam sterilization prior to use.
Indications for Use	The SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. The SI-TECHNOLOGY® SI-DESIS® X™ Sacroiliac Joint Fusion System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

Technological Characteristics	There are no significant technological differences between the subject and predicate devices. The technological design is identical to the predicate based in terms of indications for use, principles of operation, inputs, and outputs. The only difference is the subject device is the addition of select implant offerings. The subject device implants were compared to the predicate in intended use, indications for use, function and technology and it was demonstrated that they are substantially equivalent.
Performance Testing	No new testing was required to support substantial equivalence. Justifications and adoptions were provided to support that testing previously provided as part of K241813 remained applicable to the subject device. The following adoptions / justifications were performed: • Steam Sterilization Adoption • Static Shear Finite Element Analysis (FEA) • Cross Sectional Area Assessment • Pushout Testing Worst Case Assessment and Adoption • Usability Worst Case Assessment and Adoption The results of these studies show the subject device is substantially equivalent to the predicate devices.
Conclusions	Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the subject device is as safe and as effective as the legally marketed predicate.