November 20, 2025

SI Solutions, LLC.
% Austin Howell
Engineer
Engineer Aid
1384 Dallas Cir. SW
Marietta, Georgia 30064

Re: K251365
Trade/Device Name: OptumSI Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: October 22, 2025
Received: October 22, 2025

Dear Austin Howell:

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,

MAZIAR SHAH-MOHAMMADI -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251365

Device Name

OptumSI Implant System

Indications for Use *(Describe)*

The OptumSI Implant System is intended for sacroiliac fusion for the following conditions:
- 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.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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.

510(k) #: K251365

510(k) Summary

Prepared on: 2025-11-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SI Solutions, LLC.
Applicant Address	1010 Club Village Dr. Suite C Columbia MO 62503 United States
Applicant Contact Telephone	310-403-4139
Applicant Contact	Mr. Craig Meyer
Applicant Contact Email	meyer.craig@aol.com
Correspondent Name	Engineer Aid
Correspondent Address	1384 Dallas Cir. SW Marietta GA 30064 United States
Correspondent Contact Telephone	404-788-1602
Correspondent Contact	Mr. Austin Howell
Correspondent Contact Email	austin@engineer-aid.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OptumSI Implant System
Common Name	Sacroiliac Joint Fixation
Classification Name	Sacroiliac Joint Fixation
Regulation Number	888.3040
Product Code(s)	OUR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193524	SI BONE iFuse Implant System	OUR

Device Description Summary

21 CFR 807.92(a)(4)

The OptumSI Implant System consists of a cannulated diamond-shape, titanium implant (Ti-6Al-4V ELI, ASTM 3001) with a porous surface. The implant is available in varying lengths and are provided sterile and individually packaged. The system utilizes a transverse approach with a lateral or lateral-to-medial trajectory from the ilium to the sacrum. Instruments are provided as a reprocessable set to assist with gaining access and delivering the implant as intended. The principle operation is based on the diamond-shape and porous surface which are designed to prevent and minimize motion of the sacroiliac (SI) joint, thereby stabilizing the joint or fracture. The mechanism of action is that the interference fit allows for fixation, stabilization, and fusion.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The OptumSI Implant System is intended for sacroiliac fusion for the following conditions:
- 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.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The OptumSI Implant System has indications for use that are substantially equivalent to the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The OptumSI Implant System has nearly identical technological characteristics as those of the primary predicate device. Both devices are constructed from the same material, use the same manufacturing processes, and have the same principle of operation. The design of the two devices differ in shape and topological features. These design differences have not negatively affected the ability of the OptumSI Implant to meet the necessary performance requirements.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Mechanical performance testing was conducted on the device per ASTM F3574-22 Standard Test Methods for Sacroiliac Joint Fusion Devices. This is a recognized consensus standard from the FDA for the product code OUR, which is the applicable product code for the device of interest. The device tested in static cantilever bending, dynamic cantilever bending, and pullout testing per Annex 2 of the standard.

In characterizing the performance of the device in compliance with ASTM F3574-22, it was observed that the worst-case construct exhibited performance characteristics that met the acceptance criteria. With that, it can be concluded that the device is adequate at maintaining integrity during the expected loading conditions that would be experienced clinically. It is the conclusion of the development team that the device is substantially equivalent to the predicate at providing treatment for the intended use.