Surgentec, LLC
Andrew Shoup
Chief Operating Officer
911 Clint Moore Rd
Boca Raton, Florida 33487

June 7, 2023

Re: K230446
Trade/Device Name: TiLink-L 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 10, 2023
Received: March 10, 2023

Dear Andrew Shoup:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.06.07 08:45:23 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230446

Device Name
TiLink-L SI Joint Fusion System

Indications for Use *(Describe)*
The TiLink-L Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Information

Submitter: Surgentec, LLC
911 Clint Moore Rd
Boca Raton, FL 33487
Telephone: 561-990-7882

Contact: Andrew Shoup
Chief Operating Officer
Telephone: 561-990-7882
Email: ashoup@surgentec.com

Date Prepared: February 1, 2023

Name of Device

Device Proprietary Name: TiLink-L SI Joint Fusion System

Device Common Name: Sacroiliac Joint Screw

Classification Regulation: Class II; 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Panel: Orthopedic

Product Code: OUR

Legally Marketed Predicate Device

Primary Predicate: SI-LOK SACROILIAC JOINT FIXATION SYSTEM
GLOBUS MEDICAL, INC.
510(k) number: K112028

Additional Predicate: SIJFuse™ Sacroiliac Joint Fusion Device System
SpineFrontier, Inc.
510(k) number: K150017

Device Description

The TiLink-L Joint Fusion System contains various orthopedic instruments to assist the user in implanting a titanium sacroiliac implant into the sacroiliac joint to fixate the joint. There are various sacroiliac implant sizes available for implanting to accommodate a range of sacroiliac joint sizes and geometries.

Indication for Use

The TiLink-L Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Technological Characteristics and Substantial Equivalence

The subject TiLink-L Joint Fusion System is substantially equivalent to the predicate SIJFuse™ Sacroiliac Joint Fusion Device System previously cleared in 510k K150017 and the SI-LOK SACROILIAC JOINT FIXATION SYSTEM previously cleared in 510k K112028. Both devices are contained in a device tray containing the required components to action the device, not provided sterile but can be sterilized via steam sterilization prior to use and are intended for surgical treatment of the sacroiliac joint. All characteristics and indications between the TiLink-L Joint Fusion System and the predicates are the same, therefore the subject device is substantially equivalent to the predicate devices.

Performance Data

The following non-clinical performance data were provided to demonstrate substantial equivalence of the subject device to the predicates.

- Biocompatibility per ISO 10993-1:2018
- Sterilization validation per ISO 17665-1:2006/(R) 2013
- Mechanical static and dynamic testing per ASTM F543 and ASTM F1264
- V/V Mechanical and Safety Testing

Conclusion

The design characteristics of the TiLink-L Joint Fusion System does not raise different questions of safety and effectiveness. Non-clinical study data supports that the device is substantially equivalent to predicate devices. This data supports that the TiLink-L Joint Fusion System is substantially equivalent to the predicate device.