September 25, 2023

Surgentec, LLC
Mr. Travis Greenhalgh
Chief Executive Officer
911 Clint Moore Rd
Boca Raton, Florida 33487

Re: K230857
Trade/Device Name: TiLink-P 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: September 12, 2023
Received: September 12, 2023

Dear Mr. Travis Greenhalgh:

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,

Colin O'neill -S

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)*
K230857

Device Name
TiLink-P SI Joint Fusion System

Indications for Use *(Describe)*
The TiLink-P SI 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.

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510(k) Summary

Submitter Information

Submitter: Surgentec, LLC
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Telephone: 561-990-7882

Contact: Travis Greenhalgh
Chief ExecutiveOfficer
Telephone: 561-990-7882
Email: travis@surgentec.com

Date Prepared: March 28, 2023

Name of Device

Device Proprietary Name: TiLink-P SI Joint Fusion System

Device Common Name: Sacroiliac Joint Fixation

Classification Regulation: 21 CFR §888.3040

Class: II

Panel: Orthopedic

Product Code: OUR

Legally Marketed Predicate Device

Primary Predicate: Catamaran Sacroiliac Joint Fixation System, Tenon Medical, Inc. (K180818)

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

Device Description

The TiLink-P SI Joint Fusion System contains various orthopedic instruments to assist the user in implanting a titanium sacroiliac implant into the sacroiliac joint to transfix the joint.

The SurGenTec TiLink-P SI Joint Fixation System includes TiLink Implants and associated Instruments. The TiLink implant may be used standalone. The TiLink Implants are manufactured from titanium alloy and include the TiLink Locking Screw and the TiLink Compression Anchor. The TiLink Compression Anchor is designed to transfix the ilium and sacrum while compressing the SI joint. The TiLink Compression Anchor includes an opening to insert the TiLink Locking Screw. During the Procedure, the TiLink

Compression Anchor is positioned so that it spans the ilium and sacrum, the TiLink Locking Screw is inserted through the TiLink Compression Anchor and along the SI Joint via a posterior approach. Bone graft material is placed within the TiLink implant to facilitate bone growth.

Indication for Use
The TiLink-P SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Technological Characteristics and Substantial Equivalence
The TiLink-P SI Joint Fusion System is substantially equivalent to the primary predicate (Catamaran Sacroiliac Joint Fixation System, K180818) and the secondary predicate (SILO TFX MIS Sacroiliac Joint Fixation System, K221047) devices with respect to indications, design materials, function, and performance.

Performance Data
The following non-clinical performance data were provided to demonstrate substantial equivalence to the predicate devices.

- Biocompatibility per ISO 10993-1:2018
- Sterilization validation per ISO 17665-1:2006/(R) 2013
- Mechanical static and dynamic testing per ASTM F3574 and ASTM F543
- Side-by-side cadaver study to support performance of device

Conclusion
The subject device and the predicate devices have the same intended use, technological characteristics, function, and comparable performance. The data included within this submission demonstrate substantial equivalence to the predicate devices listed above.