



December 27, 2024

SurGenTec LLC
Berny Villejeune
Engineering Manager
911 Clint Moore Rd
Boca Raton, Florida 33487

Re: K243835

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: December 12, 2024
Received: December 13, 2024

Dear Berny Villejeune:

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,

Ethan R. Naylor -S

For Ronald P. Jean, Ph.D.

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

Submission Number (if known)

K243835

Device Name

TiLink-P SI Joint Fusion System

Indications for Use (Describe)

The TiLink-P 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

Device Trade Name: TiLink-P Joint Fusion System

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

Contact: Berny Villejeune
Engineering Manager
SurGenTec, LLC
Telephone: 561-990-7882
Email: berny@surgentec.com

Date Prepared: December 18, 2024

Classifications: 21 CFR §888.3040

Class: II

Product Codes: OUR

Primary Predicate: TiLink-P SI Joint Fusion System, SurGenTec, LLC, K242141

Additional Predicates: TiLink-L SI Joint Fusion System, SurGenTec, LLC, K230446, K231831

MSB Sacroiliac Joint Fusion Device, Medtronic Sofamor Danek, Inc., K110472

Indications For Use:

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

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. The SurGenTec TiLink-P SI Joint Fixation System includes TiLink Implants and associated Instruments (sterile or non-sterile). The TiLink-P SI Joint Fusion System may be used via lateral or posterior oblique. Bone graft material is used with the TiLink-P SI Joint Fusion System to facilitate bone growth.

Predicate Device:

It has been determined through the contents of this Special 510(k) that the subject TiLink-P SI Joint Fusion System is substantially equivalent to the following legally marketed predicate devices:

- **Primary Predicate:** TiLink-P SI Joint Fusion System, SurGenTec, LLC, K242141
- **Additional Predicate:** TiLink-L SI Joint Fusion System, SurGenTec, LLC, K230446, K231831
- **Additional Predicate:** MSB Sacroiliac Joint Fusion Device, Medtronic Sofamor Danek, Inc., K110472

Performance Testing Summary:

The subject TiLink-P SI Joint Fusion System has been assessed via the following testing:

- Axial Pullout Testing per ASTM F543
- Static and Dynamic Cantilever Test per ASTM F3574
- Sterilization, Packaging, and Shelf-Life Validations
- Biocompatibility Assessment per ISO 10993

Substantial Equivalence:

The TiLink-P Joint Fusion System is substantially equivalent to the cited predicate devices with respect to indications, design materials, function, and performance.

Conclusion:

The TiLink-P SI Joint Fusion System is substantially equivalent to the predicate devices as the subject and predicate devices have the same intended use, same technological characteristics, and are made of the same materials. The data included in this submission demonstrates substantial equivalence to the legally marketed predicate device cited. The TiLink-P SI Joint Fusion System is as safe, as effective, and performs as well as, or better, than the predicate devices.