March 20, 2026

SurGenTec, LLC
Richard Sharp
911 Clint Moore Rd.
Boca Raton, Florida 33487

Re: K253604
Trade/Device Name: TiLink-L Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 19, 2026
Received: February 19, 2026

Dear Richard Sharp:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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.

510(k) Number *(if known)*
K253604

Device Name
TiLink-L Navigation Instruments

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.

The TiLink-L Navigation Instruments are intended to be used with the TiLink-L Joint Fusion System during surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System S8, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy. Fluoroscopy is intended to be used for navigating final implant placement.

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) Summary

Device Trade Name:	TiLink-L Navigation Instruments
Manufacturer:	SurGenTec LLC. 911 Clint Moore Road Boca Raton, FL 33487
Contact:	Richard Sharp Jr. Director of Engineering (561) 990-7882
Date Prepared:	March 19, 2026
Panel:	Orthopedic
Class:	II
Product Codes:	OLO
Regulation:	21 CFR 882.4560
Primary Predicate:	Medtronic Navigated Manual Reusable Instruments (K161210)
Reference Device:	TiLink-L Joint Fusion System (K231831)
Reference Device:	Ion 3D (K243265)
Reference Device:	GraftGun Universal Graft Delivery System (GDS) (K243580)

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

The TiLink-L Navigation Instruments are intended to be used with the TiLink-L Joint Fusion System during surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System S8, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy. Fluoroscopy is intended to be used for navigating final implant placement.

Device Description:
The TiLink-L Navigation Instruments include a Drill Bit, Drill Guide, and Inserter and are specifically designed to be used with the TiLink-L Joint Fusion System Implants. The TiLink-L Navigation Instruments are to be used with the NavLock Instruments and Medtronic StealthStation System S8. The TiLink-L Joint Fusion System is provided sterile (single use) and non-sterile (reusable) and the TiLink-L Navigation Instruments are manufactured from Stainless Steel per ASTM F899.

Comparison of Technological Characteristics:
The subject TiLink-L Navigation Instruments have the same intended use, fundamental scientific technology, material, and Indications as the primary predicate, Medtronic Navigated Manual Reusable Instruments (K161210).

Non-Clinical Performance Testing:
The following tests were conducted to demonstrate substantial equivalence:

- Positional Accuracy Testing per ASTM F2554
- Dimensional and Engineering Analyses
- Sterilization Assessments per ISO 17664 and per ISO 11137
- Cleaning Assessments per ASTM F3208
- Packaging Assessments per ISO 11607-1, -2
- Shelf-life Assessments per ISO 11607
- Biocompatibility Assessments per ISO 10993-1

The subject devices met the pre-determined acceptance criteria for all tests and assessments. The results of all performance testing demonstrates that the TiLink-L Navigation Instruments are substantially equivalent to the cited predicate device.

Substantial Equivalence:
The data presented within the subject 510(k) demonstrates that the TiLink-L Navigation Instruments are substantially equivalent to the cited predicate device. The subject and predicate have the same intended use, have the same fundamental scientific technology, and are manufactured from the same material. The results of the performance testing demonstrated that the TiLink-L Navigation Instruments are able to perform as intended and are substantially equivalent to the predicate device.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device and reference device, the TiLink-L Navigation Instruments are as safe and effective as the legally marketed predicate device.