



July 24, 2026

SurGenTec, LLC
Richard Sharp Jr.
Director of Engineering
911 Clint Moore Rd.
Boca Raton, Florida 33487

Re: K262121
Trade/Device Name: Ion-L Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 23, 2026
Received: June 23, 2026

Dear Mr. 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,

Shumaya Ali -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262121

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Please provide the device trade name(s).

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Ion-L Navigated Instruments

Please provide your Indications for Use below.

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The Ion-L Navigated Instruments are intended to be used with the Ion-L System Facet Implants during spinal surgery to assist the surgeon in precisely locating anatomical structures, specifically the lumbar facet joint, in either open or minimally invasive procedures. These instruments are specifically 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 must be used to confirm final implant placement.

Please select the types of uses.

- ☒ Prescription Use ([21 CFR 801 Subpart D](#))
☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☐ Children (2 years old to < 12 years old)
☐ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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510(k) Summary

Device Trade Name: Ion-L Navigated Instruments

Manufacturer: SurGenTec LLC.
911 Clint Moore Road Boca
Raton, FL 33487

Contact: Richard Sharp Jr.
Director of Engineering
(561) 990-7882

Date Prepared: July 15, 2026

Panel: Orthopedic

Common Name: Orthopedic Stereotaxic Instrument

Class: II

Product Codes: OLO

Regulation: 21 CFR 882.4560 (Stereotaxic Instrument)

Primary Predicate: Ion-C Navigated Instruments (K260329)

Reference Device: Ion-L (K261209)

Indications For Use:

The Ion-L Navigated Instruments are intended to be used with the Ion-L System Facet Implants during spinal surgery to assist the surgeon in precisely locating anatomical structures, specifically the lumbar facet joint, in either open or minimally invasive procedures. These instruments are specifically 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 must be used to confirm final implant placement.

Device Description:

The Ion-L Navigated Instruments include a locator, drills and inserters. Each Instrument is intended to be used with the Medtronic NavLock Array. The Ion-L Navigated Instruments are provided sterile or non-sterile and are used during the surgical procedure to implant Ion-L System Facet Implants. The Ion-L Navigated Instruments are intended to assist the surgeon in locating

anatomical structures, specifically the lumbar facet joint, in either open or minimally invasive procedures. The Ion-L Navigated Instruments are intended to be used with StealthStation S8.

Comparison of Technological Characteristics:

The subject Ion-L Navigated Instruments have the same intended use, fundamental scientific technology, critical geometry, materials, and Indications as the cited predicate devices.

Performance Testing:

The following performance testing has been conducted to demonstrate substantial equivalence:

- Sterilization Validation per ISO 17664, ISO 11137
- Biocompatibility Assessments per ISO 10993
- Engineering Analyses and Evaluations of Critical Geometry

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

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device and reference device, the Ion-L Navigated Instruments are substantially equivalent to the cited predicate device.