June 11, 2026

SurGenTec, LLC
Guilherme Pires
VP of Operations
911 Clint Moore
Boca Raton, Florida 33487

Re: K261209
Trade/Device Name: Ion-L
Regulatory Class: Unclassified
Product Code: MRW
Dated: April 13, 2026
Received: April 13, 2026

Dear Guilherme Pires:

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,

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

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.	K261209

Please provide the device trade name(s).

Ion-L

Please provide your Indications for Use below.

The Ion-L System facet implants are intended to be placed bilaterally through a posterior surgical approach and spans the facet interspace. Ion-L is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) from L3 to S1 in skeletally mature patients who have failed conservative care.

Ion-L is intended to provide temporary stabilization as an adjunct to a 1-level interbody lumbar fusion. The Ion-L is intended to be used with an FDA-cleared intervertebral body fusion device implanted at the same level. The Ion-L is intended for use with autogenous and/or allogenic bone graft.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
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)

510(k) Summary

Submitter: SurGenTec, LLC
911 Clint Moore Rd
Boca Raton, FL 33487
(561) 990 7882

Official Correspondent: Mr. Guilherme Pires
VP of Operations
SurGenTec, LLC
911 Clint Moore Rd
Boca Raton, FL 33487

Date Prepared: June 9, 2026

Trade Name: Ion-L

Common Name: Facet Spinal Device

Classification Name: Unclassified

Product Code: MRW

Primary Predicate: PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840)

Additional Predicate: FFX Facet Fixation System (K252153)

Reference Device: Ion-C (K251714)

Reference Device: Ion 3D (K241416, K243265, K240086, K211855)

Device Description:

The Ion-L is intended for bilateral stabilization of the facets from L3-S1 at 1-level. Ion-L is intended to be placed bilaterally through a posterior approach and is intended to span the facet joint interspace.

Ion-L is designed for controlled non-impact placement to minimize damage to the implant and anatomy. The Ion-L offers a zero profile implant design which includes fenestrations and open barrels allow for bone graft integration and fusion. When Ion-L is implanted the joint is kept in a neutral position, reducing the risk of joint expansion. Ion-L engagement features are designed to resist implant expulsion.

Ion-L includes various Implant types and sizes, which can be provided sterile or non-sterile. All Implants are manufactured from Ti6Al4V per ASTM F136. The Ion-L Instruments are offered in various configurations, including single-use (provided sterile), and reusable (provided non-sterile). The Ion-L Instruments may be used to rasp or decorticate bone from the facets and/ or transverse processes and for the delivery of bone graft.

Indications for Use:
The Ion-L System facet implants are intended to be placed bilaterally through a posterior surgical approach and spans the facet interspace. Ion-L is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) from L3 to S1 in skeletally mature patients who have failed conservative care.

Ion-L is intended to provide temporary stabilization as an adjunct to a 1-level interbody lumbar fusion. The Ion-L is intended to be used with an FDA-cleared intervertebral body fusion device implanted at the same level. The Ion-L is intended for use with autogenous and/or allogenic bone graft.

Technological Similarities and Differences:
The Ion-L Implants and the predicates PMT Facet Fixation System, Lumbar (PMT FFS-LX), and FFX Facet Fixation Systems are intended to be placed in the facet joint interspace for temporary stabilization as an adjunct to fusion. The Ion-L, PMT FFS-LX, and FFX Facet Fixation System are intended to be used at 1-level. The Ion-L, PMT FFS-LX and FFX Facet Fixation System are manufactured from titanium. The Ion-L features a screw based design while the PMT FFS-LX and FFX Facet Fixation System are cage based designs.

Substantial Equivalence:
Retrospective clinical data on the subject device were provided in support of this submission. The clinical outcomes demonstrated the Ion-L to have substantially equivalent safety and effectiveness profile compared to predicates when treating the same patient population.

The subject Ion-C is substantially equivalent to the previously cleared PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840) and FFX Facet Fixation System (K252153) with respect to intended use, materials, design, and function.

Performance Testing of the Ion-C:
The following tests have been performed on the Ion-L:

- Static and Dynamic Three Point Bend Testing per ASTM F1264-16
- Axial Pushout Testing per ASTM F543
- Static Compression Bending per ASTM F1264
- Torque to Failure Testing per ASTM F543
- Insertion and Removal Torque Testing per F543
- Clinical Data has been provided on the subject device for the proposed Indications

Conclusion:
The information provided in this submission supports the conclusion that the Ion-L is substantially equivalent to the predicate devices.