December 4, 2024

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

Re: K243265
Trade/Device Name: Ion 3D
Regulatory Class: Unclassified
Product Code: MRW, FMF, HTR
Dated: September 27, 2024
Received: October 15, 2024

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 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,

Colin O'neill -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243265

Device Name

Ion 3D

Indications for Use *(Describe)*

The Ion 3D Facet Screw may be used in conjunction with the Ion 3D GraftRasp to perform posterior spinal fusion. The Ion 3D GraftRasp may be used to rasp or decorticate bone from the facets and/or transverse processes and for the delivery of hydrated allograft or autograft. The Ion 3D Facet Screw is indicated for the posterior surgical treatment at C2-S1 (inclusive) spinal levels for the following:

- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis or failed previous fusions which are symptomatic
- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facet with instability

The Ion 3D Facet Screw is intended for use with bone graft material (allograft, or autograft).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter: SurGenTec, LLC
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Official Correspondent: Mr. Richard Sharp
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Date Prepared: October 15, 2024

Trade Name: Ion 3D

Common Name: Facet Screw Spinal Device, Piston Syringe and Bone Rasp

Classification: Unclassified
21 CFR 880.5860

Product Code: MRW, FMF, HTR

Primary Predicate: Ion 3D Facet Screw (K241416)

Additional Predicate: Ion Facet Screw System (K211855)

Device Description:
The Ion 3D contains various sized facet screws with and without graft windows for bilateral stabilization of the facets from C2-S1. The Ion 3D is provided in various configurations, including single-use, and reusable. The Instruments are offered in sterile and non-sterile configurations. All implants are manufactured from Ti6Al4V per ASTM F136.

The purpose of this 510(k) is to add new Ion 3D Facet Screws and new instruments to the system.

Indications for Use:
The Ion 3D Facet Screw may be used in conjunction with the Ion 3D GraftRasp to perform posterior spinal fusion. The Ion 3D GraftRasp may be used to rasp or decorticate bone from the facets and/or transverse processes and for the delivery of hydrated allograft or autograft. The Ion 3D Facet Screw is indicated for the posterior surgical treatment at C2-S1 (inclusive) spinal levels for the following:

- Spondylolisthesis
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- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facet with instability

The Ion 3D Facet Screw is intended for use with bone graft material (allograft, or autograft).

Substantial Equivalence:
The subject Ion 3D Facet Screw with graft windows and cannulation is substantially equivalent to the previously cleared versions in K211855 and K241416 with respect to intended use, materials, design, and function.

Performance Testing:
The following evaluations have been performed on the subject Ion 3D Facet Screws and instruments.

- A finite element analysis and engineering justifications were provided justify that the subject Ion 3D Facet Screws do not represent a new worst case for mechanical performance.
- Biocompatibility Assessment per ISO 10993
- Sterilization Validation
- Cleaning Validation

Conclusion:
The subject Ion 3D Facet Screw is substantially equivalent to the cited predicate devices.