SurGenTec, LLC
Guilherme Pires
Official Correspondent
911 Clint Moore Rd
Boca Raton, Florida 33487

February 8, 2024

Re: K240086
Trade/Device Name: Ion 3D
Regulatory Class: Unclassified
Product Code: MRW, FMF, HTR
Dated: January 11, 2024
Received: January 11, 2024

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 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.

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.02.08 09:14:48 -05'00'

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240086

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. Guilherme Pires
Vice President of Operations
SurGenTec, LLC
911 Clint Moore Rd
Boca Raton, FL 33487
Phone: 561-990-7882
Email: gui@surgentec.com

Date Prepared: February 7, 2024

Trade Name: Ion 3D

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

Classification Name: Unclassified
21 CFR 880.5860. Piston Syringe, Class II

Product Code: MRW, FMF, HTR

Primary Predicate Device: Ion Facet Screw System (K211855)

Reference Device: 3D GraftRasp System (K201900)

Device Description:

The Ion 3D contains various sized facet screws 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.

Indications for Use:

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The Ion 3D Facet Screw is indicated for the posterior surgical treatment at C2-S1 (inclusive) spinal levels for the following:

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- 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).

Substantial Equivalence:

The subject Ion 3D is substantially equivalent to the previously cleared Ion Facet Screw System in K211855 with respect to intended use, materials, design, and function. The information provided in this submission demonstrates that the Ion 3D may be used to perform posterior spinal fusion by rasping or decorticating bone from the facets and/or transverse processes, and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site. The Ion 3D is intended for use with bone graft material.

Performance Testing of the Ion 3D:

The following tests have been performed on the Ion 3D.

- Usability Testing
- Sterilization Validation
- Cleaning Validation
- Mechanical Testing per ASTM F543, ASTM F1264, and ASTM F2193
- Biocompatibility Testing
- Functionality – Common Material Test
- Rasp Functionality Test
- Volume Dispensing Verification Test
- Simulated Use Validation Testing

Conclusion:

The information provided in this submission lead to the conclusion that the Ion 3D is substantially equivalent to the predicate device.