SurGenTec, LLC
Andrew Shoup
Chief Operating Officer
911 Clint Moore Rd
Boca Raton, Florida 33487

February 25, 2022

Re: K211855
Trade/Device Name: Ion Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: January 5, 2022
Received: January 10, 2022

Dear Andrew Shoup:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211855

Device Name
Ion Facet Screw System

Indications for Use *(Describe)*
The Ion Facet Screw System 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 system is intended for use with bone graft material.

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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5.0 510(k) Summary

5.1 Submitter Information

Submitter: Surgentec, LLC
911 Clint Moore Rd
Boca Raton, FL 33487
Telephone: 561-990-7882

Contact: Andrew Shoup
Chief Operating Officer
Telephone: 561-990-7882
Email: ashoup@surgentec.com

Date Prepared: June 15th, 2021

5.2 Name of Device

Device Proprietary Name: Ion Facet Screw System

Device Common Name: Screw, Facet Screw Spinal Device

Classification Regulation: Unclassified, Pre-Amendment

Panel: Orthopedic

Product Code: MRW

5.3 Legally Marketed Predicate Device

Primary Predicate: ALLY™ Facet Screws
PROVIDENCE MEDICAL TECHNOLOGY, INC.
510(k) number: K163374

Additional Predicate: SS Fenestrated Facet Screw System
SPECTRUM SPINE, LLC
510(k) number: K132126

5.4 Device Description

The Ion Facet Screw System contains various sized facet screws for bilateral stabilization of the facet joints from levels C2 through S1, inclusive. The system is supplied with various orthopedic instruments that assist the user in implanting a titanium facet screw into the facets to fixate the facet joint. There are various facet screw sizes available for implanting to accommodate a range of facet joint sizes and geometries.

5.5 **Indication for Use**

The Ion Facet Screw System 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 system is intended for use with bone graft material.

5.6 **Technological Characteristics and Substantial Equivalence**

The subject Ion Facet Screw System is substantially equivalent to the predicate SS Fenestrated Facet Screw System previously cleared in 510k K132126 and the ALLY™ Facet Screws previously cleared in 510k K163374. Both devices are contained in a device tray containing the required components to action the device, not provided sterile but can be sterilized via steam sterilization prior to use and are intended for posterior surgical treatment of the facet. All characteristics and indications between the Ion Facet Screw System and the predicates are similar, therefore the subject device is substantially equivalent to the predicate devices.

5.7 **Performance Data**

The following non-clinical performance data were provided to demonstrate substantial equivalence of the subject device to the predicates.

- Biocompatibility per ISO 10993-1:2018
- Sterilization validation per ISO 17665-1:2006/(R) 2013
- Mechanical static and dynamic testing per ASTM F543, ASTM F1264, and ASTM F2193.
- V/V Mechanical and Safety Testing

5.8 **Conclusion**

The design characteristics of the Ion Facet Screw System do not raise different questions of safety and effectiveness. Non-clinical study data supports that the device is substantially equivalent to predicate devices.