September 3, 2020

SurGenTec, LLC
Andrew Shoup, COO
911 Clint Moore Road
Boca Raton, Florida 33847

Re: K201900
Trade/Device Name: 3D GraftRasp System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, HTR
Dated: July 6, 2020
Received: July 8, 2020

Dear Mr. 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,

Laura C. Rose, Ph.D.
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

4.0 Indications for Use Statement

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)*
TBD K201900

Device Name
3D Graftrasp System

Indications for Use *(Describe)*
The 3D GraftRasp System is intended to be used in orthopedic procedures to rasp or decorticate bone from the transverse processes and/or facets, and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the 3D GraftRasp System is provided below.

5.1 Submitter Information:

Submitter:	SurGenTec, LLC 911 Clint Moore Rd Boca Raton, FL 33487 Telephone: (561) 990-7882
Contact:	Andrew Shoup COO Phone 561-990-7882 Email: ashoup@surgentec.com
Date Prepared:	July 6th, 2020

5.2 Name of Device

Device Proprietary Name:	3D GraftRasp System
Device Common Name:	Piston Syringe and Bone Rasp
Classification Regulation	21 CFR 880.5860 Class II
Classification name:	Piston Syringe
Panel:	General & Plastic Surgery
Product Code:	FMF, HTR

5.3 Legally Marketed Predicate Device

Predicate: 3D GraftRasp System
Surgentec, LLC.
Class II Device (K200431)

5.4 Device Description

The 3D GraftRasp system contains various decortication rasps, graft pushers, a bone funnel, tools, and dilators. The 3D GraftRasp system is compatible with the Graftgun Universal Graft Delivery System for graft delivery to the surgical site. The decortication rasps can be used to rasp or decorticate bone from transverse processes and/or facets. After rasping, a 5cc or 7.5cc graft tube can be inserted into the rasp lumen to extrude graft from the tip of the rasp. A set of optional sequential dilators and rasp pushers may also be provided to aid in the use of the decortication rasp. A bone funnel may optionally be used to extrude graft through the rasps instead of the graftgun.

5.5 Indication for Use

The 3D GraftRasp System is intended to be used in orthopedic procedures to rasp or decorticate bone from transverse processes and/or facets, and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

5.6 Technological Characteristics and Substantial Equivalence

Substantial Equivalence Topic	3D GraftRasp System	3D GraftRasp System
510(k)	TBD	K200431
Regulation Description	21 CFR 880.5860	21 CFR 880.5860
Device Name	3D GraftRasp System	3D GraftRasp System
Product Code	FMF, HTR	FMF, HTR
Classification	Class II	Class II
Indications for Use	The 3D GraftRasp System is intended to be used in orthopedic procedures to rasp or decorticate bone **from the transverse processes and/or facets**, and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.	The 3D GraftRasp System is intended to be used in orthopedic procedures to rasp or decorticate bone and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.
Single Use	Yes / No*	Yes / No*
Sterility	Steam Sterilization	Steam Sterilization
Patient Contact Material	Medical Grade: • Stainless Steel – 316L, 304 per ASTM F899-12b, passivated per ASTM A967-13 • Nitinol Superelastic per ASTM F2063, passivated per ASTM A967-13 • **Ti64 per ASTM F136-13, passivated per ASTM A967-13.**	Medical Grade: • Stainless Steel – 316L, 304 per ASTM F899-12b, passivated per ASTM A967-13 • Nitinol Superelastic per ASTM F2063, passivated per ASTM A967-13
Packaging	Packaged in sterilization tray, sterilized and cleaned prior to each use via autoclave. Replacement parts shipped in nonsterile packaging including labeling, IFU, and cleaning instructions. Need to be assembled, cleaned and sterilized prior to use.	Packaged in sterilization tray, sterilized and cleaned prior to each use via autoclave. Replacement parts shipped in nonsterile packaging including labeling, IFU, and cleaning instructions. Need to be assembled, cleaned and sterilized prior to use.
Operating Principle	The user can dilate tissue for easier access to the surgical site. The decortication rasp is then used to remove cortical bone by manually scraping the bony anatomy. Once the bony anatomy is prepared, graft is applied using the Graftgun Universal	The user can dilate tissue for easier access to the surgical site. The decortication rasp is then used to remove cortical bone by manually scraping the bony anatomy. Once the bony anatomy is prepared, graft is applied using the Graftgun Universal

	Graft Delivery Device. It's inserted into the rasp and delivers graft through the rasp lumen directly to the prepared surgical site. The shape of the rasp allows to access to adjacent **transverse processes and/or facets** during decortication and graft delivery.	Graft Delivery Device. It's inserted into the rasp and delivers graft through the rasp lumen directly to the prepared surgical site. The shape of the rasp allows to access to adjacent vertebral bodies or other bony anatomy during decortication and graft delivery.
Components	Orthopedic Rasp, Dilators, Pushers, Graft Funnel, **Tools**	Orthopedic Rasp, Dilators, Pushers, Graft Funnel

*Some components of the GraftRasp System are designed to be reusable while others are single use such as the replaceable rasp teeth and the flexible tip of the rasp pusher.

5.7 Performance Data

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

- Biocompatibility per ISO 10993-1:2018
- Sterilization validation per ISO 17665-1:2006/(R) 2013
- Bench Testing
    - Functionality - Common Material Test
        - Various graft materials were tested to ensure the Graftgun can successfully extrude them through the various rasps of the 3D GraftRasp System. For each rasp, the Graftgun was able to successfully extrude the graft materials using an acceptable hand force.
    - Rasp Functionality Test
        - The rasping surface of the rasp was tested on a sample bone block to ensure the worst case scenario rasp of the 3D GraftRasp System is capable of bone decortication without failure. The rasp was able to successfully decorticate a portion of the bone block without failure of either the teeth of the rasping surface or of the main rasp body.
    - Volume Dispensing Verification Test
        - The Graftgun Universal Graft Delivery system was tested to ensure an accurate amount of bone graft was dispensed with every squeeze of the trigger. It was justified that using the Graftgun along with either rasp and the accompanying graft pusher of the 3D GraftRasp System was adequate to maintain the acceptance criteria
    - Simulated Use Validation Testing
        - Seven simulated use validation studies were conducted with physician who are considered intended users. The validations were completed on cadavers and/or sawbones models to simulates typical use of the system in an operating room environment. These validations were designed to get feedback from a potential user and to validate the devices, labeling, usability, human factors, and technique. The user is supplied with a complete the appropriate labeling and Surgical

Technique. The validations demonstrated that the GraftRasp System was able to be effectively used in orthopedic procedures to rasp or decorticate bone from transverse processes and/or facets, and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site. It also evaluated multiple physicians' feedback on the safety and efficacy of the device, labeling and training.

5.8 Conclusion

The design characteristics of the 3D GraftRasp System do not raise different questions of safety and effectiveness. This data supports that the 3D GraftRasp System is substantially equivalent to the predicate device.