DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 19, 2017

SurGenTec, LLC
Mr. Travis Greenhalgh
CEO
7601 N Federal Highway # 150B
Boca Raton, Florida 33487

Re: K170675
Trade/Device Name: Graftgun Universal Graft Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 3, 2017
Received: March 6, 2017

Dear Mr. Greenhalgh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See *PRA Statement below.*

51O(k) Number *(if known)*
K170675

Device Name

Graftgun Universal Graft Delivery System

Indications for Use *(Describe)*

The Graftgun Universal Graft Delivery System is intended to be used 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.

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Premarket Notification 510(k) Summary

Graftgun Universal Graft Delivery System

1. Submitter Information:

Owner:	SurGenTec, LLC
Address:	7601 N Federal Hwy # 150B Boca Raton, FL 33487
Contact:	Travis Greenhalgh, CEO
Telephone:	(916) 759-7999
Email:	travis@SurGenTec.com
Date Submitted:	March 3, 2017

2. Name of Device:

Trade Name:	Graftgun Universal Graft Delivery System
Common Name:	Graft Delivery Device
Regulation Number:	21 CFR 880.5860
Regulation Name:	Syringe, Piston
Regulatory Class:	Class II
Product Code:	FMF
Proposed Panel:	General Hospital

3. Legally Marketed Predicate Device:

Predicate #1:	K161568 - Bone Solutions Mixing and Delivery System [Bone Solutions, Inc.; cleared 09/16/2016]
Predicate #2:	K142661 - Bi-Portal Bone Graft Delivery System [Spinal Surgeries Strategies, LLC; cleared 12/11/2014]

4. Device Description

The Graftgun Universal Graft Delivery System is a sterile, single-use, disposable device intended for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

The device system consists of: a graft tube for containing and delivering the desired graft material to the surgical site; a plunger to express the graft material from the graft tube; an actuating handle to advance the plunger down the length of the graft tube via a ratcheting mechanism; and an end cap to retain the graft material in the graft tube until ready for use. The system also contains a syringe style loading device for loading the graft tube with graft material.

The system is designed such that the graft tube can be filled with the desired graft material, attached to the actuating handle and plunger for use, then removed and refilled or replaced with a new graft tube. The kit comprises two graft tubes. One

graft tube is capable of containing 5.0 cc of graft material and the second can contain up to 7.5 cc. Both graft tubes are marked with a graduated scale to measure the volume of graft placed. The graft tube does not have a Luer lock mechanism; the device does not require a needle or similar attachment, the graft tube contents being expressed directly from the tip of the graft tube into the graft site.

Components are made of one or more of the following materials: polycarbonate, polypropylene, self-lubricating silicone, stainless steel, acrylonitrile butadiene styrene, and silicone elastomer.

The device is packaged in a thermoformed tray with a Tyvek lid. Each tray is then packaged individually in a Tyvek-PE film pouch and an outer paperboard carton. The packaged device system is sterilized via gamma irradiation.

5. Indications for Use

The Graftgun Universal Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

6. Technological Characteristics and Substantial Equivalence

The Graftgun Universal Graft Delivery System is substantially equivalent to the predicates, the devices having the same intended use and basic method of operation. The table below compares the indications and key technological attributes of the subject device to the predicates.

Comparator	**New Device** Graftgun System	**Predicate #1** Bone Solutions [K161568]	**Predicate #2** Bi-Portal [K142611]
Product Code; Common Name	FMF; Syringe, Piston (21 CFR 880.5860)		
Indications for Use	Intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.	Intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.	Intended for the delivery of hydrated allograft or autograft to an orthopedic surgical site.
Intended Use	Bone graft application to an orthopedic surgical site in an operating room environment		
Mechanism of Operation	Graft material expressed from graft tube via a plunger, operated by a ratchet-actuated handle. Material expressed from graft tube directly to graft site.	Graft material expressed from graft tube via a plunger, operated by either thumb pressure or a rotary assist drive. Device requires attachment to a Luer compatible device for	Graft material expressed from graft tube via a plunger, operated by thumb or palm pressure. Material expressed from graft tube directly to graft site.

Comparator	**New Device** Graftgun System	**Predicate #1** Bone Solutions [K161568]	**Predicate #2** Bi-Portal [K142611]
		dispensing graft material to the graft site.	
Sterility	Sterile, single use only; SAL 10^{-6}; γ radiation	Sterile, single use only; SAL 10^{-6}; EO gas	Sterile, single use only; SAL 10^{-6}; EO gas
Patient-Contact Materials	Polypropylene, polycarbonate	Polypropylene, polycarbonate	Polypropylene
Volume	Up to 7.5ml in graft tube	Up to 14.0 ml	Up to 4.0 ml in graft tube

7. Conclusion

The Graftgun Universal Graft Delivery System is substantially equivalent in intended use, principal of operation, and materials to the Bone Solutions Mixing and Delivery System and Bi-Portal Bone Graft Delivery System predicate devices. The difference in plunger actuation and method of sterilization are minor and do not raise any new safety or effectiveness issues for the Graftgun Universal Graft Delivery System for its intended indications.