May 10, 2018

SurGenTec, LLC
% Stephen Inglese
Quality Solutions and Support
PO Box 8271
Holland, Michigan 49422

Re: K180937
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: April 10, 2018
Received: April 10, 2018

Dear Stephen Inglese:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

K180937

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)*
NA K180937

Device Name
Graftgun Delivery Universal Graft 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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 Graft and Syringe Prefilled Tubes is provided below.

Device Common Name:	Graft Delivery Device
Device Proprietary Name:	Graftgun Universal Graft Delivery System
Submitter:	SurGenTec, LLC 7601 N Federal Hwy #150A Boca Raton, FL 33487 Telephone: 561-990-7882
Contact:	Stephen W Inglese CEO, Founder Quality Solutions and Support, LLC Phone: 561-251-0876 Email: swi@qss-llc.com
Date Prepared:	March 21, 2018
Classification Regulation	21 CFR 880.5860 Class II
Panel:	Orthopedics or General Hospital
Product Code:	FMF
Predicate Device:	K170675 – Graft Delivery Device This predicate has not been subject to a design related recall.

Device Description:

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

Indication 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.

Comparison of Technological Characteristics with the Predicate Device:

The graft tube as demonstrated in Figure 1 is made up of:
Figure 1, the dispensing unit is comprised of: a graft tube 5cc 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 a loading cap to retain the graft material in the graft tube while it is filled by the loading device. The syringe graft tubes also have a radiopaque ring marker (not pictured) 2.0mm from the graft tube tip to allow for visualization of the graft tube position under X-ray.

Figure 1

Figure 1 Fully assembled Graft Gun dispensing unit. The unit graft tube is to the left and the base of the plunger is shown to the right. Upon squeezing the trigger mechanism on the handle, the plunger is advanced down the length of the graft tube to express the graft material from the graft tube tip into the intended graft site. The graft tube is 7.17 inches in length with a diameter of .350 inches. The component is made up of medical grade polypropylene.

The graft syringe as demonstrated in Figure 2 is made up of:

The loading device, shown in Figure 2, also is a syringe style system. It has a large syringe tube that can be filled easily by the clinician with the intended graft material, a rotary-style plunger to express the material, and an end cap that attaches to both the filler graft tube and delivery graft tube for loading the delivery graft tube with graft material.

Figure 2

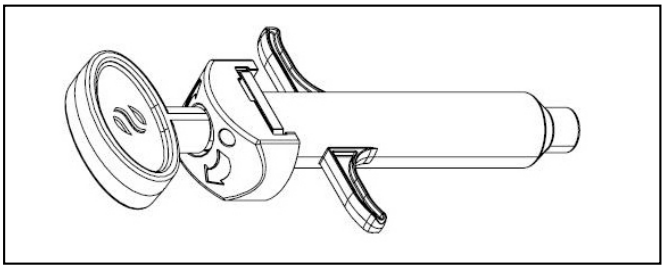

Figure 2 The Graftgun loading device (Syringe Tube). Rotating the plunger causes it to advance down the length of the graft tube, forcing the graft material out and into the filler graft tube (not shown) by means of end cap, which attaches to both graft tubes. The large open bore of the loading syringe makes graft expression into the filler graft tube easier than if using a more standard Luer-type syringe. The syringe is 4.538 inches in length with a diameter of .716 inches. The component is made up of Polycarbonate material.

Technology and Characteristics Summary:
The device components called out in Figure 1 and Figure 2 provide the identical technological and characteristic use as the cleared device K170675.

Performance Data:
The following performance data was provided in support of the substantial equivalence determination:
The risk analysis method used was Failure Modes Effect Analysis (FMEA). The results of that analysis showed that after mitigation and characterization of each remaining risk's severity and probability, all remaining risks were ranked as Acceptable.
In accordance with design control procedures, design verification and validation testing of the modified device were performed based on the risk results of the risk analysis. Table 2 summarizes the identified risks for the modification and the applicable testing that was performed.

Table 2 - Summary of Identified Risk and Verification Testing for Modification

Potential Effects of Failure	Potential Cause	Action Taken
The bone graft loaded by the Bone Graft Manufacturer can not be pushed through the Graft tube	The bone graft loaded is too viscous to be pushed through the tube.	Functionality Test -Specific material (GGDVT15 Rev A performed on tubes after they have gone through the Bone Graft manufacturer's entire process. – 12.5
Device's physical properties are diminished by the Bone Graft company's manufacturing process (Ex: filling, freezing, storage temperatures, etc.)	Tube was weakened from Bone Graft manufacturer's process and the user bending the tube to reach desired graft dispensing location.	Tube Bend Test (GGDVT05 Rev A) performed on tubes after they have gone through the Bone Graft manufacturer's entire process. – 12.3
Marking on tube are rubbed off from bone graft manufacturer's process.	Markings rubbed off during Bone Graft manufacturer's process.	Ink scratch off test (GGDVT01 Rev A) performed after they have gone through the Bone Graft manufacturer's entire process. – 12.1
Marking on tube are rubbed off during use	Markings were affected during the Bone Graft manufacturer's process so they can be rubbed off easier.	Ink scratch off test (GGDVT01 Rev A) performed after they have gone through the Bone Graft manufacturer's entire process. – 12.1
Device's physical properties are diminished by the Bone Graft company's manufacturing process (Ex: filling, freezing, storage temperatures, etc.).	Tube was weakened from Bone Graft manufacturer's process so when the user squeezes handle to dispense graft it breaks the tube.	Tube burst test (GGDVT11 Rev A) and Functionality – Specific Material test (GGDVT15 Rev A) performed on tubes after they have gone through the Bone Graft manufacturer's entire process. – 12.4 and 12.5
Device's physical properties are diminished by the Bone Graft company's manufacturing process (Ex: filling, freezing, storage temperatures, etc.).	Connection with tube was weakened from Bone Graft manufacturer's process which allowed the ring to fall off.	Ring Pull Off Test (GGDVT02 Rev A) performed on tubes after they have gone through the Bone Graft manufacturer's entire process. – 12.2
Cracks. Breaks. Handles on syringe break.	The assembly was weakened from Bone Graft manufacturer's process so the device breaks before it can load the Graft Tube	Functionality Test-Specific material test (GGDVT16 Rev A) performed on prototype and production validation. – 12.6
Reduction of components in the kit causes a reduction of sterility	Less components in the tray affects the way the components are sterilized	The gamma sterilizer (Sterigenics) advised that removing components at this scale is no issue for gamma sterilization. Because the density was decreased and packaging configuration did not change significantly, the validated gamma sterilization process should not be affected

Substantial Equivalence:

The Graftgun Universal Graft Delivery system that is the subject of this 510(k) is substantially equivalent to the previously cleared device in K170675. The only modification to the device is that the previously cleared version was demonstrating a 5cc graft or syringe tube that was loaded in the surgical facility prior to the surgical procedure. The current version that is the subject of this 510(k) is the option of having the 5cc graft or syringe tubes supplied to a registered graft facility, preloaded with graft, packaged, sterilized and shipped to the surgical facility prior to the surgical procedure. The device comparison table is provided in Table 1.

Table 1:

Substantial Equivalence Topic	Graftgun Universal Graft Delivery System	Graftgun Universal Graft Delivery System
510(k)	To Be Determined	K170675
Regulation Description	21 CFR 880.5860	21 CFR 880.5860
Device Name	Graftgun Universal Graft Delivery System	Graftgun Universal Graft Delivery System
Product Code	FMF	FMF
Classification	Class II	Class II
Indications for Use	The Graft tube is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.	The Graft tube is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.
Single Use	Yes	Yes

Sterility	Gamma irradiation to SAL of 10^{-6} **See Note 1**	Gamma irradiation to a SAL of 10^{-6}
Patient Contact Material	Medical Grade: • Polycarbonte • Polypropylene • Stainless Steel – 316L, 316F, 304H, 304HC and ABS	Medical Grade: • Polycarbonte • Polypropylene • Stainless Steel – 316L, 316F, 304H, 304HC and ABS
5cc Graft Tube	**Option of having the 5cc graft tube provided clean to a graft facility, preloaded with graft, packaged, sterilized and shipped to the surgical facility prior to the surgical procedure.**	**Loaded in the surgical facility and made ready for use.**
Syringe Tube	**Option of having the Syringe Tube provided clean to a graft facility, preloaded with graft, packaged, sterilized and shipped to the surgical facility prior to the surgical procedure.**	**Loaded in the surgical facility and made ready for use.**
Packaging	**Device tray containing the required components to action the device less those used for graft loading. Add separate packaging for both**	**Device tray containing the required components to action the device which includes those used for graft loading**

Bold – Identifies differences

Note 1 – Graft tubes are provided to a registered graft facility. Their sterilization process is validated as per their internal accepted standards prior to the prefilled tubes being shipped.

Summary:

The modification of the Graftgun Universal Graft Delivery System to provide the 5cc graft or syringe tube pre-loaded with graft, packaged, sterilized then shipped for use in the Graftgun Universal Graft Delivery System prior to the surgical procedure does not change the device functionality or the intended use of the device. The performance data support the safety of the device. Based on the device modification and indications for use, the modified device is substantially equivalent to the previous cleared Graftgun Universal Graft Delivery System in K170675.