July 13, 2020

LifeNet Health
Brittany Beasley
Global Regulatory Affairs Program Manager
1864 Concert Drive
Virginia Beach, Virginia 23453

Re: K201338
Trade/Device Name: Allograft MIS Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: May 19, 2020
Received: May 20, 2020

Dear Brittany Beasley:

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 and Part 809); 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K201338

Device Name
Allograft MIS Delivery System

Indications for Use *(Describe)*
The Allograft MIS Delivery System is intended to be used for the delivery of hydrated allograft 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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510(k) Summary

Allograft MIS Delivery System

Submitter Information:

Name:	LifeNet Health
Address:	1864 Concert Drive Virginia Beach, Virginia 23453
Contact:	Brittany Beasley, RAC Global Regulatory Affairs Program Manager
Phone:	(757) 609-4201
Email:	brittany_beasley@lifenethealth.org

Date Prepared:	July 10, 2020

Device Information:

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

Predicate Device:

Name:	Graftgun Universal Graft Delivery System (K180937)
Manufacturer:	SurGenTec LLC

Device Description:

The Allograft MIS Delivery System is a sterile, single-use, disposable graft delivery device intended for the delivery of hydrated allograft bone graft material to an orthopedic surgical site. The delivery system consists of: a cannula for containing and delivering the allograft material to the surgical site; a plunger to express the allograft material from the cannula; a dispenser to advance the plunger down the length of the cannula; and two end caps to retain the allograft material in the cannula prior to system assembly.

The cannula component is a 5 cc straight, open bore tube with a double threaded interface that mates with two end caps which are removed prior to cannula attachment to the dispenser. The dispenser is designed for single-hand, incremental delivery of graft materials and may be used to dispense multiple cannulas for a single patient.

Indications for Use:

The Allograft MIS Delivery System is intended to be used for the delivery of hydrated allograft bone graft material to an orthopedic surgical site.

Comparison of Technological Characteristics to the Predicate:

		Graftgun Universal Graft Delivery System (predicate device)	Allograft MIS Delivery System (subject device)
General	**Applicant**	SurGenTec	LifeNet Health
	Regulation No. & Name	21 CFR 880.5860, Piston Syringe	21 CFR 880.5860, Piston Syringe
	Procode	FMF	FMF
	510(K) Number	K180937	K201338
Labeling	**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.	The Allograft MIS Delivery System is intended to be used for the delivery of hydrated allograft bone graft material to an orthopedic surgical site.
	Prescription / OTC Use	Prescription Use	Prescription Use
	Type of Use	Single, Disposable	Single, Disposable
Design	**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 cannula via a plunger, operated by a ratchet-actuated handle. Material expressed from graft cannula directly to graft site.
	Patient-contact materials	**Graft tube** - Medical grade polypropylene **Loading Device/Syringe Tube** - Medical grade polycarbonate **Radiopaque ring marker** - Medical grade stainless steel - 316L, 316F, 304H, 304HC and ABS	**Graft cannula** - Medical grade polypropylene
	Graft Tube/Cannula	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.	Cannula provided sterile to a graft facility, preloaded with graft, packaged, and shipped to the surgical facility prior to the surgical procedure.
	Radiopaque marker	Yes	No
	Volume capacity	Up to 5 cc	Up to 5 cc
	Volume markings	Yes	No

		Graftgun Universal Graft Delivery System (predicate device)	Allograft MIS Delivery System (subject device)
Sterility	**Sterility Claim / SAL**	Sterile, SAL 1 x 10^{-6} **(see Note 1)**	Sterile, SAL 1 x 10^{-6} **(see Note 2)**
	Sterilization Method	Gamma irradiation	**Dispenser & Plunger:** Gamma irradiation **Cannula & End caps:** Ethylene Oxide
		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.	**Note 2:** Cannulas and end caps are provided to a registered graft facility. Their manufacturing steps conform to Current Good Tissue Practice requirements under 21 CFR 1271, Subpart D.

Performance Data:

The following testing was performed on the subject device to demonstrate substantial equivalence:

- Biocompatibility
- Dimensional and fit verification
- Functional verification
  - Mechanical extrusion
  - Simulated use
- Package performance and stability

Testing was performed on samples that represented the finished device and all specified acceptance criteria were met.

Conclusion:

The Allograft MIS Delivery System is substantially equivalent to the Graftgun dispensing unit of the Graftgun Universal Graft Delivery System in intended use, mechanism of operation, patient-contacting materials, and intent to supply the device to a registered graft facility prior to the surgical facility. The differences between the subject device and the predicate device are minor and do not impact the safety and effectiveness of the subject device as demonstrated by the provided performance testing.