



February 5, 2025

SurGenTec, LLC.  
Jason Hershman  
Engineer II  
911 Clint More Road  
Boca Raton, Florida 33487

Re: K243580

Trade/Device Name: GraftGun Universal Graft Delivery System (GDS®)  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: FMF  
Dated: November 18, 2024  
Received: November 19, 2024

Dear Jason Hershman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**JESSE  
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Jesse Muir, 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

## Indications for Use

510(k) Number (if known)

K243580

Device Name

GraftGun Universal Graft Delivery System (GDS®)

Indications for Use (Describe)

The GraftGun Universal Graft Delivery System (GDS®) is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site, via direct visualization or minimally invasive.

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

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**Date Prepared:** January 20, 2025

**Trade Name:** GraftGun Universal Graft Delivery System (GDS®)

**Common Name:** Piston / Syringe

**Classification:** 21 CFR § 880.5860

**Product Code:** FMF

**Predicate Device:** GraftGun Universal Delivery System (K170675)  
GraftGun Universal Delivery System (K180937)

### Device Description:

The GraftGun Universal Graft Delivery System (GDS®) consists of a sterile, single-use, disposable device, and non-sterile reusable Adapter Tips intended for the delivery of prepared allograft, autograft, or synthetic bone graft material to an orthopedic surgical site. The GraftGun Universal Graft Delivery System (GDS®) includes the GraftGun Dispensing Unit, Loading Device, Graft Tubes, and Adapter Tips.

### Indications for Use:

The GraftGun Universal Graft Delivery System (GDS®) is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site, viadirect visualization or minimally invasive.

### Substantial Equivalence:

The subject GraftGun Universal Graft Delivery System (GDS®) is substantially equivalent to the previous cleared versions in K170675, and K180937 with respect to intended use, materials, design, and function.

**Technological Similarities / Differences:**

The subject device incorporates a similar design, same material composition, and same principles of operation as the predicate device. The purpose of this submission was to update the naming convention of the GraftGun Universal Graft Delivery System (K170675 and K180937), make improvement modifications to our loading device and adapter tips for ease of use, modifications to our packaging configuration allowing a smaller package for ease of transport, and clear additional Letter to File changes which have been implemented to the subject device. The subject 510(k) demonstrated that the Letter to File changes, updated naming convention, and modifications of the loading device and adapter tips are substantially equivalent to the predicate device.

**Performance Testing of Subject GraftGun Universal Graft Delivery System (GDS®):**

The following assessments have been performed on GraftGun Universal Graft Delivery System (GDS®).

- Compatibility Assessments have been performed to ensure all new components are compatible with the GraftGun Universal Graft Delivery System
- Sterilization Validations per ISO 11137 and ISO 17665
- Cleaning Validations have been conducted on all reusable components
- Biocompatibility Assessment per ISO 10993
- Package Performance per ASTM D4169
- Shelf-Life Testing