August 11, 2022

Globus Medical Inc.
Dr. Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K221737
Trade/Device Name: InstaFill Graft Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 14, 2022
Received: June 15, 2022

Dear Dr. Antonacci:

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,

for

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221737

Device Name
InstaFill™ Graft Delivery System

Indications for Use *(Describe)*
The InstaFill™ Graft Delivery System is intended to be used for the delivery of 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.***

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# 510(k) Summary: InstaFill™ Graft Delivery System

**Company:** Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

**Contact:** Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

**Date Prepared:** August 10, 2022

**Device Name:** InstaFill™ Graft Delivery System

**Common Name:** Graft Delivery Device

**Classification:** Per 21 CFR as follows:
§880.5860 Piston Syringe
Product Code: FMF
Regulatory Class: II, Panel Code: 80 & 87

**Predicates:**

| | |
|---|---|
| **Primary** | Graftgun Universal Graft Delivery System (K180937) |
| **Additional** | Graftgun Universal Graft Delivery System (K170675) |
| | SIGNIFY® Bioactive (K130977) |

**Purpose:**
The purpose of this submission is to request clearance for the InstaFill™ Graft Delivery System and cartridges pre-filled with SIGNIFY® Bioactive Gel or demineralized bone matrix (DBM).

**Device Description:**
The InstaFill™ Graft Delivery System consists of a delivery device with an actuating handle, loading plunger, conical tip, and empty and pre-filled cartridges, designed to deliver graft material to an orthopedic surgical site. Cartidges are pre-filled with DBM or SIGNIFY® Gel. The delivery device and associated instruments are reusable, and the cartridges are provided sterile for single use. InstaFill™ components are manufactured from stainless steel, aluminum and PEEK, with polypropylene cartridges.

**Indications for Use:**
The InstaFill™ Graft Delivery System is intended to be used for the delivery of allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

**Performance Data:**
Testing was conducted on the InstaFill™ Graft Delivery System to confirm the device performs as intended and to demonstrate substantial equivalence to the predicate.

Testing included usability testing in a cadaver and functional verification, including axial pull-off, axial force, and burst testing. All specified acceptance criteria were met. Bacterial endotoxin testing (BET) was conducted on prefilled cartridges in accordance with ANSI/AAMI ST-72:2011. Biocompatibility of patient-contacting materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices.

**Technological Characteristics:**
The subject InstaFill™ system components and pre-filled cartridges have similar technological characteristics as the predicate devices including design, intended use, material composition, and function. The table below compares technological characteristics of the subject device to the predicate.

**Comparison of Technological Characteristics**

| Feature | Subject<br>InstaFill Graft Delivery System | Predicate<br>Graftgun<br>Universal Graft Delivery System<br>(K170675, K180937) |
|---|---|---|
| Regulation | 21 CFR 880.5860 | 21 CFR 880.5860 |
| Product Code | FMF | FMF |
| Materials | Delivery Device: Stainless steel, aluminum, PEEK<br><br>Graft Cartridges: Polypropylene | Delivery Device: Stainless steel, acrylonitrile butadiene styrene<br><br>Graft Tubes: Polypropylene |
| Mechanism of Operation | Graft material expressed from graft tube via a plunger, operated by a spring-loaded actuating trigger.<br><br>Material expressed from graft tube directly to graft site. | Graft material expressed from graft tube via a plunger, operated by a ratchet-actuated handle.<br><br>Material expressed from graft tube directly to graft site. |
| Graft Volume Capacity | 5.0cc (empty & prefilled) | 5.0cc (empty & prefilled),<br>7.5cc (empty) |
| Empty Graft Tube | Yes | Yes |
| Prefilled Graft Tube | Yes | Yes |
| Sterility | Cartridges & Conical Tip:<br>Single Use, Sterile<br>(Gamma irradiation)<br><br>Delivery Device: Reusable, Nonsterile<br>(Steam sterilized) | Delivery Device & Cannulae:<br>Single Use, Sterile<br>(Gamma irradiation) |

**Basis of Substantial Equivalence and Conclusion:**

The subject InstaFill™ Graft Delivery System is similar to the predicate devices with respect to technological characteristics, performance, design, and intended use. The differences in plunger actuation and method of sterilization for the delivery device are minor and do not raise any new concerns of safety or effectiveness for the InstaFill™ device for its intended indications. The information provided within this premarket notification supports substantial equivalence to the predicate devices.