May 1, 2020

Orthofix
Troy Brooks, RAC
Director, Regulatory Affairs
3451 Plano Parkway
Lewisville, Texas 75056

Re: K200606
Trade/Device Name: O-GENESIS Graft Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 6, 2020
Received: March 9, 2020

Dear Troy Brooks:

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)*
K200606

Device Name
O-GENESIS™ Graft Delivery System

Indications for Use *(Describe)*
The O-GENESIS 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.

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510(k) Summary

O-GENESIS™ Graft Delivery System

510(k) Owner Information:

Name:	Orthofix
Address:	3451 Plano Parkway Lewisville, TX 75056
Phone Number:	214-937-2047
Fax Number:	214-937-3322
Email:	TroyBrooks@Orthofix.com
FDA Registration Number:	2183449
Contact Person:	Troy Brooks, RAC Director, Regulatory Affairs Orthofix

Date Prepared:	April 24, 2020

Name of Device:

Trade Name / Proprietary Name:	O-GENESIS Graft Delivery System
Common Name:	Graft Delivery Device
Classification Name:	Piston Syringe
Product Code:	FMF
Regulatory Class:	Class II – 21 CFR 880.5860
Review Panel:	General Hospital
Predicate Device:	K170675 - GraftGun Universal Graft Delivery System (SurGenTec, LLC)

Reason for 510(k) Submission:

Orthofix is submitting this Traditional 510(k) premarket notification for the new O-GENESIS Graft Delivery System.

Device Description:

The O-GENESIS Graft Delivery System is designed to deliver allograft, autograft or synthetic bone graft material to an orthopedic surgical site. The system consists of a loading syringe, a loading plunger, a loading funnel, a delivery cannula and a delivery gun with an actuating trigger handle. The system is provided sterile and is for single-use only.

Indications for Use:

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

Technological Characteristics of the Device Compared to the Predicate Device:

The technological characteristics of the O-GENESIS Graft Delivery System are similar to the predicate device in terms of intended use, indications for use, and fundamental technology, including basic design, sterility and operating principle. There are no significant differences between the subject device and the predicate that raise new issues regarding safety or effectiveness. The table below compares the key technological characteristics of the subject device to the predicate device.

Comparator	**Subject Device** O-GENESIS Graft Delivery System (K200606)	**Predicate Device** GraftGun Universal Graft Delivery System (K170675)
Product Code	FMF	FMF
Classification	Class II - 21 CFR 880.5860	Class II - 21 CFR 880.5860
Intended Use	Delivery of graft material to an orthopedic surgical site.	Delivery of graft material to an orthopedic surgical site.
Operating Principle	Graft material expressed from a cannula via a plunger, operated by a ratchet-actuated handle. Graft material expressed from the cannula directly to the surgical site.	Graft material expressed from a graft tube via a plunger, operated by a ratchet-actuated handle. Graft material expressed from a graft tube directly to the surgical site.
Volume Capacity	Up to 6.6ml in cannula	Up to 7.5ml in graft tube (cannula)
Direct Patient Contacting Material	HDPE DMDA-8904 HEALTH+ HEPE DMDA-8907 NT7 (High Density Polyethylene)	Polypropylene Polycarbonate
Single-Use	Yes	Yes
Sterility	Provided Sterile Gamma Irradiation SAL 10^{-6}	Provided Sterile Gamma Irradiation SAL 10^{-6}

Performance Data:

Testing was conducted for the O-GENESIS Graft Delivery System to confirm the device performs as intended. Testing was performed using test units representative of the finished devices. Testing included simulated use, functional verification, and biocompatibility evaluation.

Simulated use testing included loading of bone graft material into the cannula and delivery of bone graft material from the cannula using the graft delivery gun. Testing was successful with all acceptance criteria met.

Functional verification testing based on design requirements and risk analysis was performed and included:

- Delivery Gun Ratchet Plunger force
- Syringe Body/Stopper force
- Threaded Components interface
- Plunger Push Rod strength
- Plunger T-Handle strength
- Syringe Body strength

Functional verification testing was successful with all acceptance criteria met.

A biocompatibility evaluation was performed in accordance with ISO 10993-1:2009, Biological Evaluation of Medical Devices – Part 1, and included testing for the following biocompatibility endpoints; Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity and Material-Mediated Pyrogenicity. Based on the evaluation and testing results the O-GENESIS Graft Delivery System is biocompatible and meets the requirements of ISO 10993-1:2009.

Conclusion:

Based upon similarities in intended use, indications for use, and fundamental technology, including basic design, sterility and operating principle, the O-GENESIS Graft Delivery System is substantially equivalent to the predicate device.