September 7, 2021

MD3 LLC
Mary Ann Greenawalt
Head of Quality
3650 Coral Ridge Drive, Suite 107
Coral Springs, Florida 33065

Re: K210997
Trade/Device Name: PREFERX Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 29, 2021
Received: July 30, 2021

Dear Mary Ann Greenawalt:

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,

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)*

K210997

Device Name

PREFERX Delivery System

Indications for Use *(Describe)*

The PREFERX 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.

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*5*10(k) Summary: PREFERX™ Delivery System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	July 29, 2021
Submitted By	MD3 LLC 3650 Coral Ridge Drive Ste 107 Coral Springs, FL 33065 1.561.703.2311
Primary Contact	Mary Ann Greenawalt 3650 Coral Ridge Drive Ste 107 Coral Springs, FL 33065 1.503.318.7722 maryann@md3inc.com
Trade Name	PREFERX™ Delivery System
Common Name	Graft Delivery Device
Classification Name	Syringe, Piston
Class	II
Product Code	FMF
CFR Section	21 CFR section 880.5860
Device Panel	General and Plastic Surgery
Primary Predicate Device	K170675 Graftgun Universal Graft Delivery System, SurGenTec, LLC
Reference Device	K180937 Graftgun Universal Graft Delivery System, Surgentec, LLC
Device Description	The PREFERX Delivery System is a single use pre-sterilized and disposable system consisting of a Feeder including a CC Body, Stand, and Funnel; a Reduction Sleeve; a BC-Sleeve and BC-Sleeve Cap, used to load the graft material into the Biologic Cartridge. The Biologic Cartridge contains and delivers the graft material to the surgical site. A Plunger expresses the graft material from the Biologic Cartridge through an actuating trigger on the Gun that advances the Plunger down the length of the Biologic Cartridge via a ratcheting mechanism. The system is designed such that the Biologic Cartridge can be filled with the desired graft material, attached to the Gun and Plunger for use, then removed and refilled during the same procedure. The Biologic Cartridge does not have a Luer lock mechanism; the device does not require a needle or similar attachment; the Biologic Cartridge contents being dispensed directly from the tip of the Biologic Cartridge into the graft site. The device is packaged in a thermoformed tray with a Tyvek lid. Each tray is then packaged individually in an outer paperboard carton. The PREFERX Delivery System is a single use pre-sterilized, disposable system intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

Materials	Clear Polycarbonate - ASTM F997-18 ABS GA850 (Acrylonitrile Butadiene Styrene) – USP Class VI Stainless steel - ASTM F899-12b
Intended Use	Apply bone graft to an orthopedic surgical site in an operating room environment.
Substantial Equivalence Claimed to Predicate Devices	The PREFERX Delivery System is substantially equivalent to the predicate devices in terms of intended use, design, and materials used.
Indications for Use	The PREFERX Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

Summary of the technological characteristics compared to predicate

	GraftGun Universal Graft Delivery (predicate)	**PREFERX Delivery System (proposed)**	**Same/Similar/Different as predicate**
Sponsor/Submitter	SurGenTec	MD3 LLC	N/A
FDA Regulation	21 CFR 880.5860 Piston Syringe	21 CFR 880.5860 Piston Syringe	Same
FDA Product Code	FMF	FMF	Same
FDA Classification	Class II	Class II	Same
K Number	K170675	TBD	N/A
Indications for Use	The GraftGun 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 PREFERX Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.	Same
Single Use	Yes	Yes	Same
Sterilization Method	Gamma irradiation to SAL of 10^{-6}	Gamma irradiation to SAL of 10^{-6}	Same

	Patient Contact Material (transient use in surgical suite)	Medical Grade: • Polycarbonate • ABS • Polypropylene • Stainless Steel – 316L, 316F, 304H, 304HC • Radiopaque ring	Medical Grade: • Polycarbonate • ABS	The proposed device is comprised of fewer patient contacting materials than the predicate device. The absence of patient contacting material: polypropylene and a stainless-steel radiopaque ring is not a significant change in materials or design and does not raise questions of safety and effectiveness. All component materials have a long history of use in medical devices. Both products use ABS & polycarbonate.
	Volume	Up to 7.5cc in graft tube	Up to 5.0cc in graft tube	If more graft is needed the PREFERX cartridge may be reloaded during the same procedure.
	Operating Principle	Graft material expressed from graft tube via a plunger, operated by a ratchet-actuated handle. Material expressed from graft tube to graft site.	Graft material expressed from graft tube via a plunger, operated by a ratchet-actuated handle. Material expressed from graft tube to graft site.	Same

Non-clinical Test Summary

Performance data, including worst-case scenario, was provided in support of the substantial equivalence determinations. To further support substantial equivalence, we used the FMEA method to identify risks and characterize the severity and probability. The risks were reduced and are ranked as Acceptable. MD3 design control procedures, design verification and validation testing of the device were performed based on the results of the risk analysis. The following summarizes the identified risks and the applicable testing that was performed.

Summary of Identified Risk and Verification Testing

Potential Effect of Failure	**Potential Cause**	**Action Taken**
Inflammation, redness and swelling, sometimes accompanied by heat and pain	Incompatible materials	Biocompatibility Testing Certification included in DHR
Graft is not applied to surgical site; graft must be applied another way – prolonged surgery	Gun is not properly assembled Biologic Cartridge is plugged	Perform visual/functionality test at incoming inspection Perform burst and functionality test
Fusion of bone may not occur, or heterotopic bone may form	Dimensions of cartridge are not correct resulting in incorrect volume of graft Volume markings are not applied accurately Teeth on plunger too small	Perform visual/functionality test at incoming inspection Records of compliance for dimensional certifications

	Patient becomes infected	No or inadequate sterilization method or cycle	Certificate of Sterilization included in DHR Sterilization validation Ink Test
	Chills to fever to swelling or sepsis	Endotoxins remain after sterilization	Bacterial endotoxin test
	Delivery system is plugged from contents – prolonged surgery	Wrong material placed in cartridge	The device has a fail-safe mechanism to avert breakage of cartridge.
Clinical Test Summary	No clinical studies were performed		
Conclusion:	MD3 LLC considers the PREFERX Delivery System to be as safe and effective and perform at least as well as the legally marketed predicate device when used as intended. The systems, predicates and proposed, are designed so that the Biologic Cartridge can be filled with the desired graft material, attached to the Gun and the Plunger, and delivered to the orthopedic surgical site. Substantial equivalence to the predicate device is based upon the similarities in design, principles of operation, technology, materials and indications for use.		

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