DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 7, 2015

Micromedics Incorporated
Ms. Amy L. Peterson
Senior Regulatory Affairs Specialist
1270 Eagan Industrial Road, Suite 120
Saint Paul, Minnesota 55121

Re: K151543
Trade/Device Name: Graft Delivery Device with Integrated Stylet
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 4, 2015
Received: June 8, 2015

Dear Ms. Peterson:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151543

Device Name
Graft Delivery Device with Integrated Stylet

Indications for Use *(Describe)*
The graft preparation and delivery device is intended for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as IV fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components as deemed necessary by the clinical use requirements.

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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K151543 - 510(K) SUMMARY

Date of Summary Preparation: July 3, 2015

510(k) Applicant/Submitter	Contact Person
Micromedics, Inc. d/b/a Nordson Medical 1270 Eagan Industrial Road St. Paul, MN 55121-1385 Tel: 651-452-1977; Fax: 651-452-1787 Establishment Registration #2183425	Amy L. Peterson, M.A. Sr. Regulatory Affairs Specialist Micromedics, Inc. d/b/a Nordson Medical 1270 Eagan Industrial Road St. Paul, MN 55121-1385 Tel: 651-405-2182; Fax: 651-452-1787

General Information			
Trade Name	Graft Delivery Device with Integrated Stylet	Common Name	Graft Delivery Device
Classification Information	Syringe, Piston per 21 CFR 880.5860 (Class II)	Product Code	FMF
		Panel	General Hospital
Predicate Devices	Micromedics Inc's Graft Delivery System, K100754, cleared June 9, 2010 Biomet Biologics' CDO™ and Graft Preparation System, K072330, cleared December 6, 2007		

Device Description

The Graft Delivery Device with Integrated Stylet is a sterile, single-use, disposable device intended for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as IV fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components as deemed necessary by the clinical use requirements.

The Graft Delivery Device with Integrated Stylet consists of a syringe body, plunger with integrated stylet, tapered end cap, funnel, cap plug, and cannula. Hydration components (hydration tube or hydration adapter) are present in some configurations. Components are made of one or more of the following materials: acrylonitrile butadiene styrene (ABS), polycarbonate, polypropylene, self-lubricating silicone, and 304 Stainless Steel.

The device is packaged in a thermoformed tray with a Tyvek lid. Each tray is then packaged in a labeled individual poly/Tyvek pouch. Five (5) pouched trays are then put into a shelf box and then a cardboard shipper box. Like the graft delivery device from K100754, the Graft Delivery Device with Integrated Stylet is sterilized using ethylene oxide.

K151543 - 510(K) SUMMARY

Intended Use / Indications

The graft preparation and delivery device is intended for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as IV fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components as deemed necessary by the clinical use requirements.

Substantial Equivalence Comparison

The Graft Delivery Device with Integrated Stylet is substantially equivalent to the predicate devices in the following characteristics:

- Operational mode
- Basic Scientific Technology
- Intended Use
- General physical characteristics

Summary of Non-Clinical Performance Data

The Graft Delivery Device with Integrated Stylet was evaluated through design verification and biocompatibility testing. Biocompatibility testing performed in accordance with ISO 10993 – *Biological evaluation of medical devices, Part 1 – Evaluation and tests (2009)* show the device is considered safe for use for its intended biocontact. Non-clinical testing included the tests listed below and showed the test articles met the pre-defined acceptance criteria, therefore demonstrating the mechanical integrity and suitability of the device for its intended use and over the labeled shelf life.

Testing was conducted for the following:

- Plunger Force
- Stylet Force
- Closed System Leak
- Vented System
- Secondary Thumb Tab Force
- Cannula Atraumatic Tip
- Dimensional Testing
- Cap Plug/Tapered End Cap/Syringe Finger Flange Strength
- Plunger Thumb Pad Strength
- Cannula/Tapered End Cap Strength
- Hydration Adapter/Tapered End Cap Strength
- Hydration Tube/Tapered End Cap Strength
- Stylet Torque
- Stylet Buckling
- Hydration Tube Strength
- Sterilization
- Shelf life
- Packaging

Summary of Clinical Performance Data

None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

As evidenced by the successful completion of non-clinical performance testing, the Graft Delivery Device with Integrated Stylet does not raise new questions of safety or effectiveness when compared to the predicate devices and is, therefore, substantially equivalent.