DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 11, 2016

Micromedics Inc. (d/b/a Nordson Medical)
Ms. Amy Peterson
Senior Regulatory Affairs Specialist
1270 Eagan Industrial Rd, Suite 120
St. Paul, Minnesota 55121

Re: K162077
Trade/Device Name: Laparoscopic Spray Applicator with Spinning Luers
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 22, 2016
Received: July 27, 2016

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" (21 CFR 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,

Christopher J. Ronk -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)*
K162077

Device Name
Laparoscopic Spray Applicator with Spinning Luers

Indications for Use *(Describe)*
Intended for the application of two non-homogenous liquids.

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.

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K162077 – 510(K) SUMMARY

Date of Summary Preparation: August 10, 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			
Device Name	Laparoscopic Spray Applicator with Spinning Luers		
Classification Information	Endoscope and Accessories per 21 CFR 876.1500 (Class II)	Product Code	GCJ
		Panel	General & Plastic Surgery
Predicate Device	Micromedics Inc's 360º Gas Assisted Endoscopic Applicator, K122526, cleared November 16, 2012.		

Device Description

The Laparoscopic (Lap) Spray Applicators with Spinning Luers are sterile, single-use, disposable devices that are designed to mix two non-homogeneous liquids and to allow the resulting mixture to be applied by spraying on potentially difficult to reach treatment sites subcutaneously or within the body through a trocar.

The Lap Spray Applicator with Spinning Luers consists of a lap spray applicator and a filter/tubing assembly (also called the tubing set). The Lap Spray Applicator with Spinning Luers has the following functional parts:

- Proximal hub (Y-connection) with spinning luers to connect to dual syringes (not provided) and an attachment point for the filter/tubing to the gas regulator (provided separately)
- Stainless steel shaft connecting hub to Pebax
- Flexible Pebax portion connecting stainless steel shaft to distal tip
- Fixed-position distal tip.

Lap Spray Applicator components are made from the following materials: White or Blue Polypropylene, Acrylonitrile Butadiene Styrene (ABS - regular/non-radiopaque), Acrylonitrile Butadiene Styrene (ABS) with 20% barium (radiopaque), Stainless Steel, White Nylon, Light Blue Pebax, Epoxy Adhesive. Tubing Set components are made from the following materials: Clear Medical PVC, Natural Nylon, Stainless Steel Wire Mesh, Clear Polycarbonate, Blue Nylon or Red Nylon, Clear Acrylonitrile Butadiene Styrene (ABS), Clear Acrylic, Versapor Filter Media.

The device is packaged in a thermoformed tray with a tray (Tyvek) lid. Five (5) trays are then put into a shelf box and then a cardboard shipper box. Like the device from K122526, the Lap Spray Applicators with Spinning Luers are sterilized using ethylene oxide.

K162077 – 510(K) SUMMARY

Intended Use / Indications
Intended for the application of two non-homogenous liquids.

Substantial Equivalence Comparison
The Lap Spray Applicator with Spinning Luers is substantially equivalent to the predicate device in the following characteristics:

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

Summary of Non-Clinical Performance Data
The Lap Spray Applicator with Spinning Luers 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* 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:

- Visual Inspection
- Particulate Matter
- Dimensional Verification Test
- Leak Test
- Spray Test
- Pebax/Tip Bond Strength
- Pebax/Shaft Bond Strength
- Hub/Shaft Pull Strength
- Hub/Shaft Torque Strength
- Spinning Luer Actuation Torque
- Spinning Luer Side Load
- Spinning Luer Pull Strength
- ISO 594-1 and -2 (specifically: Luer Gauge, Luer Leak, Luer Separation, Luer Ease of Assembly, Luer Override, and Luer Stress Cracking)
- Sterilization
- Shelf life

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 Lap Spray Applicator with Spinning Luers does not raise new questions of safety or effectiveness when compared to the predicate devices and is, therefore, substantially equivalent.