K123847

510(K) SUMMARY

JAN 8 2013

Date Prepared: December 5, 2012

510(k) Submitter	Contact for Official Correspondence
Micromedics, Inc. 1270 Eagan Industrial Road St. Paul, MN 55121-1385	Jodi L. Raus, MBA, RAC Tel: 651-452-1977; Fax: 651-452-1787 Email: jodi.raus@nordsonmicromedics.com

General Information			
Trade Name	Malleable Tip Endoscopic Applicator	Common Name	Endoscopic Applicator
Classification Information	Endoscope and accessories per 21 CFR 876.1500 (Class II)	Product Code	GCJ
		Panel	General & Plastic Surgery
Predicate Devices	Endoscopic Applicator, K120608 cleared on March 15, 2012 360° Gas Assisted Endoscopic Applicator, K122526, cleared on November 16, 2012		

Device Description

The Malleable Tip Endoscopic Applicator is a sterile, single-use, disposable device intended for delivering a hemostatic agent to bleeding sites. The Malleable Tip Endoscopic Applicator is the identical to predicate with the addition of a malleable tip at the distal end which allows directional placement of hemostatic agents.

The Malleable Tip Endoscopic Applicator cannula and stylet are packaged in a double sterile barrier tray configuration and sterilized using ethylene oxide. Six individually sterile packaged applicators are contained in a shelf carton along with instructions for use. This is the identical packaging configuration as the previously cleared device.

Intended Use / Indications

The Malleable Tip Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5 mm or larger trocar

Substantial Equivalence Comparison

The endoscopic applicator subject to this special 510(k) incorporates a flexible tube at the distal end of the applicator which allows for directional positioning of the tip.

Summary of Non-Clinical Performance Data

The Malleable Tip Endoscopic Applicator 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 over the labeled shelf life.

- Leak Testing
- Particulate Testing
- Volume Test
- Cannula Tissue Compliance
- Hemostatic Agent Multi-Use
- Shelf life Evaluation
- Kink Test
- Pinch Test
- Bounce Back Test
- Flexible Tip Strength
- Sterilization Validation

Substantial Equivalence Conclusion

The Malleable Tip Endoscopic Applicator does not raise new questions of safety or effectiveness when compared to the predicate device and is, therefore, substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Micromedics, Incorporated
% Ms. Jodi L. Raus
Director of Regulatory, Clinical and Quality Affairs
1270 Eagan Industrial Road, Suite 120
Saint Paul, Minnesota 55121

January 8, 2013

Re: K123847
Trade/Device Name: Malleable Tip Endoscopic Applicator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 14, 2012
Received: December 14, 2012

Dear Ms. Raus:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123847

Device Name: **Malleable Tip Endoscopic Applicator**

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
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(Division Sign-off)
Division of Surgical Devices
510(k) Number K123847