K102563

## 510(k) SUMMARY

**DATE OF SUMMARY:** October 28, 2010

MAR 15 2011

**OWNER:**
Micromedics, Inc.
1270 Eagan Industrial Road, Ste. 120
ST. Paul, MN 55121

**CONTACT PERSON:**
Tom Lopac
Manager, Quality Assurance and Regulatory Affairs
Telephone: 651-452-1977
Fax: 651-452-1787

**DEVICE TRADE NAME:** Single Cannula Extended Applicator

**COMMON NAME:** Biomaterial Applicator

**CLASSIFICATION NAME:** Irrigating Syringe

**PREDICATE DEVICE(S):**

| Device | Company | Previous 510(k) | Clearance Date |
|---|---|---|---|
| Biomaterial Spray Syringe | Micromedics, Inc. | K982372 | 7-22-1998 |

**DESCRIPTION OF THE DEVICE:**

The Single Cannula Extended Applicator has two components: an applicator instrument and a replaceable spray tip. The spray tip is assembled to the instrument by the user. The assembled applicator product is installed on a standard medical syringe, and allows fluids to be applied from the syringe to a treatment site that is otherwise difficult to access. The entire device is packaged sterile and labeled for single-use.

The applicator instrument contains a stainless steel hypodermic tube with a molded polymer luer lock connector on the input (proximal) end. It is enclosed in a stainless steel sheath that provides rigidity and allows the device to effectively seal off in a 5mm endoscopic cannula. A replaceable molded polymer spray tip is attached to the output (distal) end of the sleeve by the user. A replacement tip is included in the package.

**STATEMENT OF INTENDED USE:**
The Single Cannula Extended Applicator is intended for medical purposes to irrigate or instill fluid to a wound or body cavity.

## 510(k) SUMMARY (CONTINUED)

**TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:**
The Single Cannula Extended Applicator is identical to the predicate devices in intended use, function, method of operating and performance.

**Device Comparison Table**

| Characteristic | Current Application: Single Cannula Extended Applicator | Predicate Device: Biomaterial Spray Syringe 510(k) k982372 (exempt) |
|---|---|---|
| **Intended use** | The single Cannula Extended Applicator is intended for medical purposes to irrigate or instill fluids to a wound or body cavity. | The Biomaterial Spray Syringe is intended for medical purposes to irrigate or instill fluids to a wound or body cavity. |
| **System Components** | 1) Applicator instrument<br>2) Spray tip | 1) Spray tip |
| **Input** | Standard medical syringe | Single standard medical syringe |
| **Output** | Single spray | Single spray |
| **Power source** | None – syringe is manually activated | None – syringe is manually activated |
| **Compatibility with other devices** | 1)Used with single standard medical syringe<br>2)Fits into 5 mm endoscopic cannula | 1) Used with single standard medical syringe |
| **Materials** | Stainless steel<br>ABS polymer | ABS polymer |
| **Sterility** | Sterilized to $10^{-6}$ SAL by EO gas, single-use | Sterilized to $10^{-6}$ SAL by EO gas, single-use |
| **Biocompatibility** | Tested in accordance with ISO 10993 | Tested in accordance with ISO 10993 |

**DISCUSSION OF NONCLINICAL TESTS:**
Micromedics, Inc. conducts risk analysis and design verification tests are based on the result of these analyses. The tests performed are listed below. All test results meet the acceptance criteria and demonstrate that the device is appropriately designed for the intended use. Testing included:

- Leak test
- Flow test
- Pull test
- Fit and sealing in 5mm endoscopic cannula
- ISO-594-1 Conical fittings with 6% (Luer) taper

**DISCUSSION OF CLINICAL TESTS:**
No clinical tests have been performed on the Single Cannula Extended Applicator or the predicate. Twenty years of marketing the predicate has shown the product to be safe & effective. Nearly 23000 predicate devices have been sold in the past 3 years.

**CONCLUSION:**
The Single Cannula Extended Applicator is substantially equivalent to the predicate device(s) and does not introduce any new risks.

**510(k) STATEMENT (As Required by 807.93)**

I certify that, in my capacity as the Quality Manager for Micromedics, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signed: _____

Tom Lopac, Quality Manager

Date: 11-14-10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Tom Lopac
Manager of Quality Assurance & Regulatory Affairs
Micromedics, Incorporated
1270 Eagan Industrial Road, Suite 120
Saint Paul, Minnesota 55121-1385

MAR 15 2011

Re: K102563
Trade/Device Name: Single Cannula Extended Applicator
Regulation Number: 21 CFR 880.6960
Regulation Name: Irrigating Syringe
Regulatory Class: I
Product Code: KYZ
Dated: February 15, 2011
Received: February 16, 2011

Dear Mr. Lopac:

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.

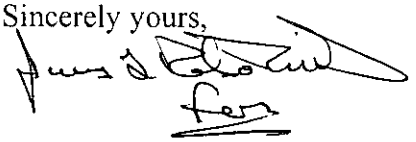
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K102563**

Device Name: **Single Cannula Extended Applicator**

Indications for Use:

***The Single Cannula Extended Applicator is intended for medical purposes to irrigate or instill fluids to a wound or body cavity.***

Prescription Use: ____ X _____ OR Over-The-Counter ___ _____
(Per 21 CFT 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/14/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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