K024052

## 510(K) Summary

FEB 21 2003

1. **Preparation Date** Dec. 3, 2002

2. **Submitted By**

Merit Medical Systems, Inc. (MMS)
1600 West Merit Pkwy.
South Jordan, UT 84095

**Contact Person/ Prepared By**
Stephanie A. Erskine
Director, Regulatory Affairs, MMS
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3. **Device Identification**

| | |
|---|---|
| **Trade Name** | Merit Medical 1-mL Syringe |
| **Common Name** | Syringe, Hypodermic Syringe |
| **Classification Name** | Piston Syringe (21 CFR 880.5860) |

4. **Predicate Device(s)** **K980580**, Becton Dickinson (BD) single-use Hypodermic and Insulin Syringes

5. **Device Description**
Merit Medical Systems 1-mL Syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male Luer Lock connector (nozzle) for attaching the female Luer connector (hub) of a hypodermic single lumen needle, or for attaching other devices with a female Luer.

6. **Intended Use**
Merit Medical 1-mL Syringes are used to inject fluids into, or withdraw fluids from, the body.

7. **Statement of Intent to Conform to ISO 7886-1;1993**
Merit Medical Systems, Inc. intends to establish that its 1-mL Syringes conform to the FDA-recognized Consensus Standard, ISO 7886-1:1993 *Sterile hypodermic needles for single use- Part 1: Syringes for manual use*, before marketing the devices. Data supporting conformance with the standard, with minor exceptions and deviations identified in the premarket notification submission, will be available before marketing the device.

8. **Conclusion**
The Merit Medical 1-mL Syringe is safe and effective for its intended use.

## 9. Substantial Equivalence/ Conformity with Standards

### 9.1 Similarities/ Differences of the proposed device when compared to the predicate:

9.1.1 Intended Use

The Becton Dickinson (B-D) General Purpose syringes are intended for general purpose fluid aspiration/ injection. Merit Medical 1-mL Syringes are used to inject fluids into, or withdraw fluids from, the body. As such, the Intended Uses of the MMS and B-D syringes are equivalent.

9.1.2 Materials

Materials used in the manufacture of MMS syringes are typically used in the manufacture of general-purpose syringes, including the predicate device.

9.1.3 Design

The design of the MMS syringe is typical for syringes, including that of the predicate.

9.1.4 Operational Principles

The MMS syringe is manually operated by advancing and withdrawing the plunger in the barrel. The operating principles are identical for all manual syringes, including the predicate.

9.1.5 Technology

The same fundamental technology is used in the design of the MMS syringes as is employed in the design of all manual syringes, including the predicate.

9.1.6 Safety and Performance

MMS has provided a statement that its syringes will conform to the requirements of ISO 7886-1:1993, an FDA- recognized consensus standard, before marketing the devices. This statement and the data that will be collected to support conformance will be used to demonstrate safety and performance in lieu of demonstrating substantial equivalence with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

Ms. Stephanie A. Erskine
Director, Regulatory Affairs
Merit Medical Systems, Incorporated
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K024052
Trade/Device Name: Merit Medical 1-mL Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: December 5, 2002
Received: December 6, 2002

Dear Ms. Erskine:

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.

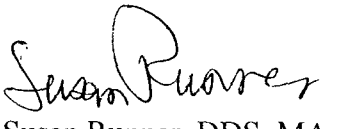
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION(S) FOR USE STATEMENT*

**Merit Medical 1-mL Syringes are used to inject fluids into, or withdraw fluids from, the body.**

Signature of 510(k) Submitter: _____

Printed Name of Submitter: Stephanie A. Erskine
Director, Regulatory Affairs
Merit Medical Systems, Inc.

Date: _____

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K024052

Division Sign-Off _____
Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use _____

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

510(k) Number: K024052