

Micro Therapeutics, Inc.
Premarket Notification 510(k): Abbreviated
1 ml Syringe



510(k) Summary of Safety and Effectiveness

MTI 1 ml Syringe

Prepared 8 April, 1999

Trade Name:	MTI 1 ml Syringe	Classification:	Class II
Generic Name:	Piston Syringe	Contact:	Maria D. Ochoa
Submitted By:	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618		Regulatory Affairs (949) 837-3700

Predicate Devices

Merit Medical Systems, Inc.: Medallion Syringe

Device Description

The MTI 1 ml Syringe is a long stroke syringe designed for injection or aspiration of fluids during diagnostic and/or therapeutic procedures. The syringe will have a male conical lock fitting to facilitate attachment to various catheters and accessories. The syringe will be provided sterile and is for single-use only.

The transparent barrel is made of a heat and chemical resistant polyolefin. The plunger is composed of a polymer resin and the piston is a silicone, non-latex rubber with a liquid silicone lubricant.

The syringe is provided as a set of three, in a sterile Tyvek peel pouch and chipboard carton. The syringes are for general use.

Indications For Use

The MTI 1 ml Syringe is intended for injection and aspiration of fluids. The syringe is designed for manual use.

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Testing

Biocompatibility of the MTI Syringe has been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the syringe when tested as an externally communicating, blood path indirect, limited exposure device.

In-vitro performance testing of the syringe included measurement of leakage, forces required to operate, verification of volume accuracy, and dimensional inspection tests. Testing of the product yielded results in conformance with the following recognized standards:

- *ISO 7886-1: Sterile Hypodermic Syringes for Single Use – Part I: Syringes for Manual Use (May 1997) and,*
- *ISO 594 : Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1 and 2 (6/86 and 5/91 resp.)*

Summary of Substantial Equivalence

The MTI Syringe is substantially equivalent to the predicate devices in intended use and principles of operation and conforms to the aforementioned consensus standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL -9 1999

Ms. Maria D. Ochoa
Regulatory Affairs
Micro Therapeutics, Incorporated
1062-F Calle Negocio
San Clemente, California 92673

Re: K991225
Trade Name: MTI 1 ml Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 8, 1999
Received: April 12, 1999

Dear Ms. Ochoa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

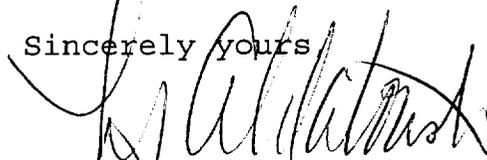
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Micro Therapeutics, Inc.
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1 ml Syringe

510(k) Number (if known): K991225

Device Name: MTI 1 ml Syringe

Indications for Use:

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Patricia Cucenite
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991225

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

(Per 21 CFR 801.109)