

K981417

JUL 17 1998

## 510(k) SUMMARY

### SAFETY AND EFFECTIVENESS SUMMARY

April 16, 1998

This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

MERIT MEDICAL

Submitted by Name/Address:

SYSTEMS, INC.

Dennis Reigle  
Regulatory Affairs Manager  
Merit Medical Systems, Inc.  
1600 West Merit Parkway  
South Jordan, UT 84095  
(801) 253-1600  
(801) 253-1684 fax

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MERIT PARKWAY

SOUTH JORDAN,

Contact Person: Same as above

UTAH 84095

Date Summary Prepared: April 16, 1998

Device Name: Squirt™ Fluid Delivery System

801-253-1600

Common Name: Catheter, Continuous Flush

FAX 801 253 1684

Trade Name: Squirt™

Classification (if known): 74 KRA

Predicate Devices: AngioDymanic® Pulse\* Spray® Pulsed Infusion System  
Merit Medical Medallion™ Syringe  
Merit Medical Check Relief Valve

Applicant Device Description:

The Squirt™ is a fluid delivery system, designed to be attached to a syringe and a catheter, to infuse controlled administration of thrombolytic agents into the peripheral vasculature. The Squirt™ facilitates repeatable and accurate delivery of thrombolytic agents where numerous doses of up to 1.0 ml are given as a part of the thrombolysis treatment regimen.

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**Applicant Device Description: - continued**

The catalog number for the Squirt™ is FDS100. The Squirt™ is packaged sterile, non-pyrogenic and has a one year shelf life. The Squirt™ is intended to be sold as a stand alone device or with the Fountain™ Infusion System, which was cleared under Merit's 510(k) K974067.

**Applicant Device Intended Use:**

The Squirt™ Fluid Delivery System is intended for the controlled administration of thrombolytic agents into the peripheral vasculature.

**Technological Characteristics:**

The Squirt™ facilitates repeatable and accurate delivery of thrombolytic agents where numerous doses of up to 1.0 ml are given as a part of the medical treatment regimen.

**Materials Comparison (Squirt™ and Merit Medallion™ Syringe)**

| Components       | Squirt™                               | Merit Medallion™ (Syringe)            |
|------------------|---------------------------------------|---------------------------------------|
| Syringe Body     | Polycarbonate                         | Polycarbonate                         |
| Syringe Plunger  | ABS (Acrylonitrile-Butadiene-Styrene) | ABS (Acrylonitrile-Butadiene-Styrene) |
| Tip Seal         | Natural Rubber                        | Natural Rubber                        |
| Rotator Assembly | Polycarbonate                         | Polycarbonate                         |

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JUL 17 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Dennis Reigle  
Regulatory Affairs Manager  
Merit Medical Systems, Inc.  
1600 West Merit Parkway  
South Jordan, UT 84095

Re: K981417  
Trade Name: Squirt™ Fluid Delivery System  
Regulatory Class: II  
Product Code: KRA  
Dated: April 16, 1998  
Received: April 20, 1998

Dear Mr. Reigle:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

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) 594-4618. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

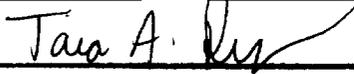
Merit Medical Systems, Inc.  
510(k) Notification:

Indications For Use:

The Squirt™ Fluid Delivery System is intended for the controlled administration of thrombolytic agents into the peripheral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

Prescription Use   
(Per 21 CFR 801.109)

510(k) Number OR 2981417 Over-The-Counter Use

(Optional Format 1-2-96)

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