



K973708

DEC 19 1997

**510(k) SUMMARY  
SAFETY AND EFFECTIVENESS SUMMARY**

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  
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SOUTH JORDAN,

**Contact Person:**

Same as above

UTAH 84095

**Date Summary Prepared:**

September 26, 1997

801-253-1600

**Device Name:**

FAX 801-253-1651

**Common Name:** PTCA Guide Wire and Accessories

**Trade Name:** TomCat™ PTCA Guide Wire, Extender™ Wire and Extension Tool

**Classification Name:** Catheter Guide Wire

**Classification:** 74DQX

**Predicate Devices:**

Device

Manufacturer

ACS Hi Torque™ 3 cm Extra S'Port Guide Wire	Advanced Cardiovascular Systems, Inc.
ACS Hi Torque™ 30 cm Standard Guide Wire	Advanced Cardiovascular Systems, Inc.
ACS Hi Torque™ 30 cm Floppy Guide Wire	Advanced Cardiovascular Systems, Inc.
SciMed Sceptor™ 3 cm Floppy Guide Wire	SciMed Life Systems, Inc.
SciMed Sceptor™ 2 cm Standard Guide Wire	SciMed Life Systems, Inc.
ACS DOC™ Guide Wire Extension 145 cm	Advanced Cardiovascular Systems, Inc.

**Intended Use:**

The TomCat™ Guide Wire is intended to facilitate the placement of interventional catheters during therapeutic intravascular procedures.

The TomCat Extender™ Wire is used to facilitate exchange of one therapeutic device for another, while still maintaining the guide wire position in the coronary vasculature.

The guide wire extension tool is a device used to facilitate the joining of a guide wire with an extension wire.

**DEVICE DESCRIPTION**

There are three guide wire designs: Coil, Tube and Fighter. Accessories include an extension wire and extension tool.

**Coil Design**

The coil design includes the following tip flexibilities: Floppy, Intermediate, Standard and X-Support. This design consists of a coated core wire gradually tapered by grinding in a multi-step process at the distal end over a 30 cm length. The distal tip of the wire is then flattened. The flattened tip dimension and the taper pattern determine the flexibility of the distal 30 cm section of the guide wire. A radiopaque helically wound coil 30 cm in length is soldered in three places to the core wire. The distal 30 cm of the wire is coated to reduce friction between the guide wire and the interventional device. The wire is manufactured in two tip configurations: a pre-shaped J-Tip for immediate use or an unmodified straight tip to allow the clinician to custom shape the tip. For the 175 cm length wires, the proximal end of the wire is tapered to accommodate attachment to the Merit TomCat™ Extender™ Wire.

**Tube Design**

The tube design includes the following tip flexibilities: Floppy, Intermediate, Standard and X Support. The coated core wire is tapered and shaped in the same manner as the coil design. However, a 3 cm radiopaque helically wound coil is soldered in two places to the core wire instead of the 30 cm coil. A tube is then bonded in two places over the remainder of the exposed area of the core wire. The distal 30 cm of the wire is coated to reduce friction between the guide wire and the interventional device. The wire is manufactured in two tip configurations: a pre shaped J-tip for immediate use or an unmodified straight tip to allow the clinician to custom shape the tip. For the 175 cm length wires, the proximal end of the wire is tapered to accommodate attachment to the Merit TomCat™ Extender™ Wire.

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**Fighter Design**

The Merit Fighter guide wire is a modification of the coil design. The coated core wire is tapered and shaped in the same manner as the coil design. However, a 3 cm long radiopaque helically wound coil is soldered to the ground core wire in 2 places, instead of a 30 cm coil. The remainder of the tapered portion of the core wire is left bare. The distal 30 cm of the wire is coated to reduce friction between the guide wire and the interventional device. The wire is manufactured in two tip configurations: a pre shaped J-tip for immediate use or an unmodified straight tip to allow the clinician to custom shape the tip. For the 175 cm length wires, the proximal end of the wire is ground to accommodate attachment to the Merit TomCat™ Extender™ Wire.

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**Extender Wire**

The Merit TomCat Extender Wire is a coated core wire, 150 cm long and has a 0.014 inch diameter. It is tapered at the distal end, where a nickel/titanium hypotube is bonded to the core wire. This hypotube mates with the proximal tapered section of the Merit TomCat™ Guide Wire.

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**Extension Tool**

The Merit guide wire extension tool provides for axial alignment between the TomCat Extender Wire and a TomCat guide wire. The tool is a flat molded piece with two tabs. One of the tabs is folded over to hold the guide wire in place in the tool's alignment channel (located in the middle of the tool). An embossed arrow on the tool shows where the end of the wire needs to be placed. The extension wire is placed in the alignment channel on the other side of the tool and the other tab is folded over holding the extension wire in place. The guide wire is then slid along the alignment channel until it is inserted into the extension wire's hypotube.

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Merit TomCat™ Specifications	
Guide Wire Diameter	0.014 inches (0.36 mm)
Guide Wire Lengths	175 cm; 300 cm
Sterile	Yes
Non-Pyrogenic	Yes
Single Use	Yes
Tip	J-Shaped or Straight
Shelf Life	2 Years

Catalog Numbers and Descriptions:

Catalog Numbers	Description
TC14F03	3 cm Opaque, straight tip, Floppy, 0.014" O.D., 175 cm long
TC14F03J	3 cm Opaque, shaped tip, Floppy, 0.014" O.D., 175 cm long
TC14F30	30 cm Opaque, straight tip, Floppy, 0.014" O.D., 175 cm long
TC14F30J	30 cm Opaque, shaped tip, Floppy, 0.014" O.D., 175 cm long
TC14F03L	3 cm Opaque, straight tip, Floppy, 0.014" O.D., 300 cm long
TC14F03LJ	3 cm Opaque, shaped tip, Floppy, 0.014" O.D., 300 cm long
TC14F30L	30 cm Opaque, straight tip, Floppy, 0.014" O.D., 300 cm long
TC14F30LJ	30 cm Opaque, shaped tip, Floppy, 0.014" O.D., 300 cm long
TC14X03	3 cm Opaque, straight tip, X-Support, 0.014" O.D., 175 cm long
TC14X03J	3 cm Opaque, shaped tip, X-Support, 0.014" O.D., 175 cm long
TC14X30	30 cm Opaque, straight tip, X-Support, 0.014" O.D., 175 cm long
TC14X30J	30 cm Opaque, shaped tip, X-Support, 0.014" O.D., 175 cm long
TC14X03L	3 cm Opaque, straight tip, X-Support, 0.014" O.D., 300 cm long
TC14X30L	30 cm Opaque, straight tip, X-Support, 0.014" O.D., 300 cm long
TC14SF03	3 cm Opaque, straight tip, Fighter, 0.014" O.D., 175 cm long
TC14SF03J	3 cm Opaque, shaped tip, Fighter, 0.014" O.D., 175 cm long
TC14SF03L	3 cm Opaque, straight tip, Fighter, 0.014" O.D., 300 cm long
TC14SF03LJ	3 cm Opaque, shaped tip, Fighter, 0.014" O.D., 300 cm long
TC14I03	3 cm Opaque, straight tip, Intermediate, 0.014" O.D., 175 cm long
TC14I03J	3 cm Opaque, shaped tip, Intermediate, 0.014" O.D., 175 cm long
TC14I30	30 cm Opaque, straight tip, Intermediate, 0.014" O.D., 175 cm long
TC14I30J	30 cm Opaque, shaped tip, Intermediate, 0.014" O.D., 175 cm long
TC14S03	3 cm Opaque, straight tip, Standard, 0.014" O.D., 175 cm long
TC14S03J	3 cm Opaque, shaped tip, Standard, 0.014" O.D., 175 cm long
TC14S30	30 cm Opaque, straight tip, Standard, 0.014" O.D., 175 cm long
TC14S30J	30 cm Opaque, shaped tip, Standard, 0.014" O.D., 175 cm long
TC14EXT	Extender Wire, 0.014" O.D., 150 cm long
TC14X03LJ	3 cm Opaque, shaped tip, X-Support, 0.014" O.D., 300 cm long
TC14X30LJ	30 cm Opaque, shaped tip, X-Support, 0.014" O.D., 300 cm long
TC14I03L	3 cm Opaque, straight tip, Intermediate, 0.014" O.D., 300 cm long
TC14I03LJ	3 cm Opaque, shaped tip, Intermediate, 0.014" O.D., 300 cm long
TC14I30L	30 cm Opaque, straight tip, Intermediate, 0.014" O.D., 300 cm long
TC14I30LJ	30 cm Opaque, shaped tip, Intermediate, 0.014" O.D., 300 cm long
TC14S03L	3 cm Opaque, straight tip, Standard, 0.014" O.D., 300 cm long
TC14S03LJ	3 cm Opaque, shaped tip, Standard, 0.014" O.D., 300 cm long
TC14S30L	30 cm Opaque, straight tip, Standard, 0.014" O.D., 300 cm long
TC14S30LJ	30 cm Opaque, shaped tip, Standard, 0.014" O.D., 300 cm long
100732	Extension Tool

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 19 1997

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, Utah 84095

Re: K973708  
TomCat™ Guide Wire  
TomCat™ Extender Guide Wire Extension tool  
Regulatory Class: II (two)  
Product Code: DQX  
Dated: September 26, 1997  
Received: September 29, 1997

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 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 (Pre-market 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 pre-market 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) 594-4648. 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,



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:

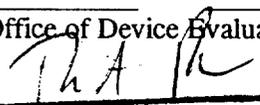
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
Division of Cardiovascular, Respiratory,  
and ~~Medical~~ Devices  
510(k) Number K973708  
~~Over-The-Counter Use~~

Prescription Use   
(Per 21 CFR 801.109)

(Optional Format 1-2-96)