



K960764

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Summary of Safety and Effectiveness

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

The assigned 510(k) number is: K960764

Applicant Information:

Date Prepared: January 20, 1997
Name: Scientific Device Manufacturer, LLC.
Address: 999 Andersen Drive, Suite 120
San Rafael, California 94901

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Device Information:

Trade Name: *Safe-Cath*
Common Name: Single- and Multi-Lumen Intravascular Catheter
Classification Name: Intravascular Catheter

Equivalent Device:

Central Venous Multi-Lumen Catheter with flexible tip (Arrow International).
Temporary Dual and Triple Lumen Catheters (Vas-Cath Incorporated).

Device Description:

The various SDM Central Venous Catheters consist of polyurethane bodies with zero to five polyurethane extension tubes. Except for the smallest French sizes of the single lumen devices, the catheters all contain an additional flexible polyurethane distal tip. The proximal end(s) of each catheter terminate in molded-on, fixed, female locking luers. Where present, the extension tubes are joined to the catheter body by insert-molded polyurethane and contain clamps for occluding the tubes. Many configurations are marked with centimeter markings to indicate insertion depth.

Catheters will be offered in "kits" which will include some or all of the following depending on configuration: Catheter, guidewire in dispenser, dilator, syringe, scalpel, suture wing, and introducer needle. The makeup of specific sets can be seen in the Appendix D of this 510(k) submission. These kits will be packaged in semi-rigid vacuum formed trays containing a heat-sealed, ethylene oxide permeable lids, or in standard Tyvek/Poly pouches, depending on the product configuration.



SDM,LLC
510(k) Submittal
Central Venous Catheters, Standard

Intended Use:

These devices are intended for various non-permanent intravascular applications including pressure monitoring, fluid administration, and blood sampling.

Comparison To Predicate Device:

Scientific Device Manufacturer's Vascular Access Catheters are substantially equivalent to currently marketed vascular access catheters with regard to intended use, materials, dimensions and mechanical properties. Predicate devices include those made by Arrow International and Vas-Cath Incorporated. No significant changes or modifications were made from those predicate devices other than the addition of two 8.5FR 5-Lumen versions. With the exception of slightly smaller lumen sizes, the 5-Lumen catheters are constructed in the same manner as the other SDM devices. SDM, L.L.C., therefore posits that its devices are equivalent in safety, effectiveness and intended use to those devices.

Signed:

Richard C. Ball

Name:

Richard C. Ball

Position:

VP Regulatory Affairs and Quality Assurance

Date:

January 20, 1997