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scientific device manufacturer, inc.

999 Andersen Drive, Suite 110
San Rafael, California 94901
Phone 415-454-9370 Fax 415-454-9380

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SUMMARY OF SAFETY AND EFFECTIVENESS

Percutaneous Catheter Introducer, Set

510(k) Premarket Notification

Trade Name: SDM Percuglide

Generic Name: Percutaneous Catheter Introducer/Set

Manufacturer: Scientific Device Manufacturer, LLC
999 Andersen Drive, Suite 110
San Rafael, CA 94901
Establishment Registration Number: TBD

Classification:

In preparation of this Premarket Notification, it was determined that devices of this generic type have been previously classified as Class II devices. No performance standards have yet been established for these products.

Product Description:

The various SDM Percutaneous Catheter Introducer/Set range in dilator tubing sized from 4 Fr to 13 Fr and in dilator lengths from 100mm to 340mm. Sheaths paired with the dilators are tapered and close fitting to facilitate maximum ease of insertion. The sheaths are offered in both FEP and Pebax depending on customer preference. The sheath hemostasis valve contains a silicone seal and is offered both with a sideport and plain. An 18ga needle and guidewire of appropriate size will also be included with each set. Dilator luers are marked with a numeral and sheath caps are colored coded to indicate french size. These sets will be packaged in semi-rigid vacuum formed trays containing a heat-sealed, ethylene oxide permeable lids.

A more economical, reduced version of the set will also be offered containing just a dilator and sheath without hemostasis valve packaged in a Tyvek/Poly chevron pouch.

Intended Use:

These devices are intended for use in percutaneous introduction of various catheters and/or guidewires into the vasculature.

Rationale for Substantial Equivalence:

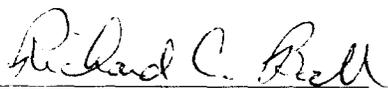
Scientific Device Manufacturer's Percutaneous Catheter Introducer/Sets are substantially equivalent to currently marketed introducer sets with regard to intended use, materials, dimensions and mechanical properties. Dimensions, materials, and functionality have been chosen to match commonly accepted industry standards and to replicate several of the predicate devices, including those made by **Arrow International**, **Cordis Corporation** and **Cook Incorporated**. No significant changes or modifications were made from those predicate devices. SDM, LLC, therefore posits that its devices are equivalent in safety and effectiveness to those devices.

Biocompatibility Evaluation:

Materials used in Scientific Device Manufacturer's Percutaneous Catheter Introducer/Sets were chosen to be generically the same as those present in the substantially equivalent devices. Testing is currently underway by SDM for this externally communicating device (circulating blood) to show this device to be biocompatible per the requirement of ISO Standard 10993, Part 1. This data will be provided to the office of Device Evaluation prior to completion of review.

Summary:

Based upon the product description and its intended use as outlined in this summary, the Scientific Device Manufacturer's Percutaneous Catheter Introducer/Kits are substantially equivalent to other vascular access kits currently in use.



Richard C. Ball

Vice President Regulatory Affairs and Quality Assurance