

K961668

510(k) Premarket Notification  
Microferret™ Catheter  
COOK INCORPORATED

NOV 4 1996

**J. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Submitted By:**

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24 April 1996

**Device:**

Trade Name: Microferret™ Catheter  
Proposed Classification Name: Class II 74 DQY

**Predicate Devices:**

The Microferret™ catheter is substantially equivalent to other devices intended for percutaneous vascular use in terms of indications for use, design, construction and materials equivalence. Specifically, this device is similar to numerous pre-Amendment COOK catheters, Tracker™ catheters (K#853997, K#862117, K#874751), manufactured by Target Therapeutics®, San Jose, California, Evolution™ Microcatheters (K#953114) manufactured by Boston Scientific, Watertown, Massachusetts, Venture™ Infusion Catheters (K#931335) manufactured by Scimed Life Systems and distributed by Boston Scientific, Watertown, Massachusetts and others.

**Device Description:**

The Microferret™ catheter is used for percutaneous access to small vessel, distal anatomy. Its single lumen construction provides graduated stiffness, from proximal being stiff to distal being very soft. The material used to construct this device is polyethylene with a graduated transition of flexibility along the shaft. The proximal hub of the catheter is designed to conform with Luer lock standards (ANSI) which are compatible with commercially available syringes. These materials are widely used in catheter device manufacturing and their biocompatibility has been verified. In addition, design validation studies have been performed to assure the device can be expected to perform its intended function when used according to the recommendations in the suggested instructions for use provided with the device.

**Summary of Clinical Use**

This device has been marketed in Europe since 1992 by a European manufacturing firm owned by COOK Group Incorporated. There has been good clinical success with the device in its worldwide use to date. The firm has identified the primary risks of devices such as the Microferret™ catheter and have included these potential risks in the device labeling. These risks are not specific to the Microferret™ catheter, but apply to vascular catheters in general. There have been no adverse health effects associated with the use of this catheter during its marketing history.

**Substantial Equivalence**

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by COOK INCORPORATED. This device will undergo sterilization similar to the devices currently marketed and distributed. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.