

K964859

**Section 4**

**Summary of Safety and Effectiveness**

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)  
Prepared April 2, 1996

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**I. General Provisions**

Submitter's Name and Address	SCIMED Life Systems, Inc. One SCIMED Place Maple Grove, Minnesota 55311
Contact Person	Angela Raun (612) 494-2456
Classification Name	Diagnostic Intravascular Catheters (21CFR Part 870.1200)
Common or Usual Name	Diagnostic Intravascular Catheter
Proprietary Name	SCIMED® 5 French IMPULSE™ Angiographic Catheters

**II. Name of Predicate Devices** SCIMED® 5 French EXPO™ Angiographic Catheter, and Cordis® Corporation 5 F Infiniti™ Angiographic Catheter

**III. Device Description**

The 5 French SCIMED IMPULSE Angiographic Catheters will be available in 3 models; 0.045" ID Selective curve styles, 0.047" ID Selective curve styles, and the 0.045" ID Pigtail and Multipurpose curve styles whose tip ID tapers from 0.045" to 0.041" distally. Curve styles will be available with optional side holes.

The shafts of all 3 models utilize common biocompatible materials and consist of the following three layers: 1) The inner layer provides a smooth surface to allow for dye delivery and ease of guide wire movement. The Selective models utilize Pebax® for the inner layer, while the Pigtail and Multipurpose catheters utilize a Polyurethane/Pebax coextrusion, 2) The middle layer is made of braided stainless steel wire that extends from the shaft to the tip to provide torque control, kink resistance and support, and 3) the outer layer, which is also manufactured from Pebax, provides stiffness and curve retention. Radiopaque materials are utilized in the inner shaft, outer shaft and tip to allow visualization of the catheter during the procedure.

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The tips of the Selective models are made from polyurethane, while the multipurpose and pigtail tips are composed of Pebax. Both tips are radiopaque to allow visualization during a procedure. The tips are heat fused to the distal end of the shaft.

The catheters utilize a polycarbonate hub and Pebax strain relief. The hub is molded to the proximal end of the catheter shaft. The devices will be provided sterile and are intended for one procedure use only.

### IV. Intended Use

The SCIMED IMPULSE Angiographic Catheters are designed to provide a pathway to be used for delivering contrast media to selected sites in the vascular system during an angiographic procedure.

### V. Summary of Technological Characteristics

The 5 French SCIMED IMPULSE Angiographic Catheters are a modification of SCIMED's currently marketed 5 French EXPO Angiographic Catheters. Changes are summarized as follows:

- The ID has been increased in one Selective model to 0.047".
- The inner shaft material has been changed from Polyurethane/Pebax to Pebax in the Selective models.
- Radiopaque loading components have been changed for the inner shaft layer, outer shaft layer, strain relief and tip material.
- A UV stabilizer has been added to the primary shaft material of all new models.
- The colorants in the primary shaft, inner shaft, catheter tip and strain relief have been changed.
- The inner shaft material durometers have been modified on the Selective models.
- The distal 1" to 5" of the Selective models will decrease in shaft stiffness using transitional stiffness extrusion processing. The proximal end of the shaft will increase in shaft stiffness due to an added annealing process.
- A pigtail straightener is being provided for the pigtail models, which allows the pigtail to be introduced into the sheath more easily.
- The braid wire material has been changed to a different grade of stainless steel and the braiding pattern has been slightly modified.

### VI. Non-clinical Test Summary

Functional testing consisted of pressure burst, tip bond tensile, hub tensile, dye flow, maximum dye flow, tip coefficient of friction, force transmitted by the catheter tip, device radiopacity, and pigtail straightener peel-away force testing. Biocompatibility and shelf life testing has also been conducted. Test results verified

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that the 5 F IMPULSE Angiographic Catheters are adequate for their intended use. The 5 F IMPULSE Angiographic Catheters are considered substantially equivalent to angiographic catheters currently marketed by SCIMED and Cordis based on a comparison of intended use, the design and the results of *in-vitro* testing and evaluation.