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SCIMED®
Boston Scientific Corporation

SCIMED Life Systems, Inc.
One SCIMED Place
Maple Grove, MN 55311-1566
612-494-1700

Section Three--Summary of Safety and Effectiveness
(Pursuant to Section 12, Safe Medical Devices Act of 1990)
Prepared: April 3, 1996

I. General Provisions:

Submitter's Name and Address:	SCIMED Life Systems, Inc. One SCIMED Place Maple Grove, Minnesota 55311
Contact Person:	Deborah A. Frank (612) 494-2899
Classification Name:	Continuous Flush Catheter (21CFR870.1210)
Common or Usual Name:	Infusion Catheter
Proprietary Name: Infusion	SCIMED Dispatch Gold Coronary Catheter

II. Name of Predicate Device(s):

SCIMED Dispatch Coronary Infusion Catheter (K953133) and SCIMED UltraFuse Coronary Infusion/Guide Wire Exchange Catheter (BK940029)
LocalMed© InfusaSleeve™ Coronary Infusion Catheter (K950615)

III. Device Description:

The Dispatch Gold Coronary Infusion Catheter is a non-dilatation, over-the-wire device designed for localized delivery of solution(s), through the openings located in the distal segment, into the selected coronary artery. The device has a single lumen shaft with a distally located inflation coil 20 mm, 30 mm or 50 mm in length. The number of coils increases with length. The inflation coil, encapsulated by a thin polyurethane sheath, may be inflated to further localize or isolate delivery to subselected vasculature.

The lumen of the shaft is used to transport solutions, as well as to house an inner tube and inflation tube running the length of the shaft and situated concentrically within the lumen. The inner tube permits the use of coronary guide wires ≤ 0.014" to advance the device through the anatomy to the intended infusion site. The distal tip is tapered to facilitate the advancement of the device through the vasculature.

Radiopaque markers are located at both the proximal and distal ends of the balloon coil to assist in the placement of the device's distal assembly. Shaft locating markers are printed proximally on the outer shaft of the catheter to ensure proper placement of the distal infusion segment with respect to the guide catheter. One marker is designated by two parallel white stripes located at 100 cm and the other is designated by a single white stripe located at 90 cm from the distal tip for femoral and brachial approaches respectively.

The proximal portion of the device consists of a manifold with a blue inflation port and a yellow infusion port. The inner lumen is connected to an unmarked thru port for guide wire insertion, which also has a luer lock fitting for the connection of a Y-adapter if desired.

IV. Intended Use:

The Dispatch Gold Coronary Infusion Catheter is intended for controlled and selective infusion of solution(s), including thrombolytic agents, into the vessel.

V. Summary of Technological Characteristics:

The Dispatch Gold Coronary Infusion Catheter is a modification of the currently marketed Dispatch Coronary Infusion Catheter. The two catheters look and function alike, however the Dispatch Gold has a smaller overall outer shaft dimension and distal profile. The color of the Dispatch Gold shaft will be yellow instead of clear (natural). Other modifications include the configuration of the infusion openings and the length of the platinum marker band. The Dispatch Gold will be available in coil lengths of 20 mm, 30 mm and 50 mm with coil diameters ranging from 2.5 mm to 5.5 mm.

VI. Non-clinical Test Summary:

Testing and evaluation included infusion flow rate, inflation coil burst and distension, repeat inflation of coil assembly, catheter bond integrity and bond tensile strength, shaft diameter, inflation coil assembly profile, catheter withdrawal force and proximal mark integrity test. Test results verified that the Dispatch Gold Coronary Infusion Catheter met or exceeded all minimum requirements and is adequate for its intended use. The Dispatch Gold Coronary Infusion catheter is considered to be substantially equivalent to the currently marketed SCIMED Dispatch Coronary Infusion Catheter and the currently marketed SCIMED UltraFuse Coronary Infusion Catheter based on a comparison of intended use, design and the results of the *in vitro* testing and evaluation.