K971607

Section 4 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

JUL 24 1997

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	Angiographic Intravascular Catheter
Proprietary Name	Medi-tech® 4 and 5 French Nighthawk™ Flush Angiographic Catheters

II. Name of Predicate Devices

Medi-tech® 4 and 5 F Imager™ Tennis Racket™ Flush catheters

III. Device Description

The Medi-tech 4 and 5 French Nighthawk Flush Angiographic Catheters are available in the following dimensions and tip taper configurations. The 4 F Nighthawk catheters are tapered at the tip to be compatible with 0.035" guidewires. The 5 F Nighthawk catheters have two tapered tip configurations to be compatible with 0.038" and 0.035" guide wires.

Model	Catheter ID (ins)	Final Tip ID (ins)	Available Lengths	Sideholes
4 F Nighthawk Non-braided Flush	0.040"	tapers to 0.038"	65-100 cm	yes
5 F Nighthawk Non-braided Flush	0.049"	tapers to 0.038"	65-100 cm	yes
5 F Nighthawk Non-braided Flush	0.049"	tapers to 0.041"	65-100 cm	yes

The Nighthawk Flush catheters utilize common biocompatible materials. The Nighthawk catheter shaft is coextruded using Pebax combined with a radiopaque filler for the inner layer and Pebax with a radiopaque filler and colorant as the outer surface layer. The shaft provides a smooth surface to allow for dye flow and easy

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guide wire movement as well as stiffness and curve retention. The radiopaque materials are utilized in the shaft and tip to allow visualization of the catheter during the procedure. The catheter will be provided with sideholes and optional silicone coating applied to the exterior surface of the outer layer.

The catheters utilize a polycarbonate hub and Pebax strain relief. The hub is molded to the proximal end of the catheter shaft. A tip straightener is included as an accessory to the Flush line of catheters. The devices will be provided sterile and are intended for one procedure use only.

IV. Intended Use

The Medi-tech 4 and 5 French Nighthawk Flush 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. Non-clinical Test Summary

Functional testing consisted of pressure burst, tip bond tensile, hub tensile, dye flow, tip coefficient of friction, force transmitted by the catheter tip, radiopacity, torque, tip straightener peel-away force, and particulate and verification of the silicone coating integrity. Test results verified that the 4 and 5 French Nighthawk Flush Angiographic Catheters are adequate for their intended use. The 4 and 5 French Nighthawk Flush Angiographic Catheters are considered substantially equivalent to angiographic catheters currently marketed by Medi-tech based on a comparison of the intended use, design and results of *in-vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Angela Raun
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One SCIMED Place
Maple Grove, Minnesota 55311-1566

JUL 24 1997

Re: K971607
Trade Name: Medi-tech® and 5 French Nighthawk™ Flush Angiographic Catheters
Regulatory Class: II
Product Code: 74DQO
Dated: April 30, 1997
Received: May 1, 1997

Dear Ms. Raun:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Section 2 — Indications for Use

510(k) Number (if known) _____

Device Name: Medi-tech® 4 and 5 French Nighthawk™ Flush Angiographic Catheters

Indications for Use:

The Medi-tech® 4 and 5 French Nighthawk™ Flush 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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use_____
(Per 21 CFR 801.109)

Lynne A. Reamer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971607

(Optional Format 1-2-96)