JUL 1 4 1998

K974457

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Hewlett-Packard Scout Catheter

510(k) Summary of Safety and Effectiveness

(per 21 CFR 807.92)

1) **Submitter's Name / Contact Person:** Rob Butler
Address: 3000 Minuteman Road, Andover, MA 01810
Telephone Number: (978) 659-2785
Date Summary was prepared: November 17, 1997

2)

Trade Name	Model Number
Scout 3.2F/45 MHz Coronary Imaging Catheter .014" Compatible	M2440A-014
Scout 3.2F/45 MHz Coronary Imaging Catheter .018" Compatible	M2440A-018
Scout Imaging Catheter Patient Interface Unit (PIU)	M2401B

Common Name: Ultrasonic Diagnostic Catheter

Classification Name	CFR Number	Product Code
Diagnostic Ultrasound Transducer	21 CFR 892.1570	90 ITX
Diagnostic Intravascular Catheter	21 CFR 870.1200	74 DQO

3) **Identification of Predicate Devices:**

Manufacturer	Device	510(k) Number
Boston Scientific	MicroView II/MicroRail II 3.2/30 MHz	K942231
Boston Scientific	Sonicath 3.5F Ultrasound Imaging Catheter	K913890
Boston Scientific	Automatic Pullback Device	K933517
Boston Scientific	CVIS Catheter Pullback Device	K921879

4) **Description of the device or modification being submitted for premarket approval.**

Functionality: M2440A intravascular ultrasound imaging catheter has equivalent functionality to the predicate Boston Scientific catheters now cleared for use with M2400A; acoustic output for the M2440A operating on the M2400A is within FDA limits. The pullback functionality incorporated into the M2440A catheter and the M2401B PIU are equivalent to the predicate Boston Scientific catheters and pullback devices listed above.

Scientific Concepts: same as existing intravascular ultrasound imaging catheters and pullback devices operating on the M2400A Intravascular Ultrasound System.

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Significant Characteristics of the Modification: new patient contact materials for M2440A Intravascular Ultrasound imaging catheter. New ergonomic configuration for the motorized pullback system.

5) Statement of Intended Use: same as intended use for the predicate devices: intravascular ultrasound examination of the coronary arteries.

6) Predicate Device Comparison: M2440A is substantially equivalent to the predicate Boston Scientific catheters. The functionality of the motorized pullback integrated into the M2401B patient interface unit when operated with the M2440A catheter is substantially equivalent to the predicate device intended use . Submission includes acceptable biocompatibility and bench testing results for all changes to design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1998

Rob Butler
Regulatory Engineer
Hewlett-Packard Company
Imaging Systems
3000 Minuteman Rd.
Andover, MA 01810

Re: K974457
Scout 3.2/45 MHz Coronary Imaging Catheters
Dated: June 22, 1998
Received: June 23, 1998
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Butler:

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment E: Scout Indications for Use Form

FDA Diagnostic Ultrasound Device Indications Statement

510(k) Number (if known): K974457

Device Name(s): M2440A-018/M2440A-014 Scout 3.2F/45 MHz Coronary Imaging Catheter(s)

M2401B Patient Interface Unit

Intended Use: **The Scout catheter is intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.**

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fetal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Abdominal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intra-operative (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intra-Operative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Small Organ (prostate)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Neonatal Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Adult Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Cardiac Adult	NA	X	NA	NA	NA	NA	NA	NA	NA	NA
Cardiac Pediatric	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trans-esophageal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trans-rectal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trans-vaginal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intra-Luminal	NA	X	NA	NA	NA	NA	NA	NA	NA	NA
Trans-urethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vessel	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-Skeletal Conv.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-Skeletal Superf.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Other Indications or Modes: None

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974457

Prescription Use ✓
(Per 21 CFR 801.109)

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