Quinton imaging

AUG 25 1997

K971397

SUMMARY OF SAFETY AND EFFECTIVENESS

July 30, 1997

Contact Person: Roy A Smith, Manager of Manufacturing

Common or Usual Name: Catheter Pullback device

Proprietary Name: ViewCath™ Catheter Pullback

Product Classification: Product Code: CV 74 DQX
Wire, Guide, Catheter,
Regulatory Class II

Applicant:
Quinton Imaging Division
Quinton Instrument Company
1043 Kiel Court
Sunnyvale, California 94089
Telephone: (408) 752-8555
Fax: (408) 752-8544

Predicate Device: Cardiovascular Imaging Systems, Inc.
Catheter Pullback Device, K921879 and K933517

Description of Device: The ViewCath™ Catheter Pullback is a medical Ultrasound Intravascular transducer catheter pullback device used in conjunction with Intravascular Ultrasound system devices. The ViewCath™ Catheter has a cradle that firmly holds various catheter transducer drive motors. Upon actuation, the device pulls the motor cradle at one of two selected speeds. A medical Intravascular Ultrasound catheter attached to the drive motor is pulled back at a consistent speed to obtain multiple 2-D ultrasound images.

It is similar in design to other such catheter pullback devices. It has a motor driven mechanical screw mechanism, Intravascular Ultrasound catheter motor drive cradle, control switch and travel readout scale.

Statement of intended use: The ViewCath™ Catheter Pullback is a device used for motorized pullback of medical Ultrasound intravascular imaging catheters to assist in consistent, selectable speed, 2-D image acquisition for use by medical imaging software for longitudinal view display or 3-D reconstruction and rendering and volumetric presentation of 3-D images for diagnostic review.

6. **Statement of technological characteristics:** The Quinton Imaging ViewCath™ Catheter Pullback has no significant change in design, materials, energy source or other

technological characteristics when compared to the predicate device. It is housed in a molded plastic enclosure, 3.5" wide by 6.25" long by 1.875" (2.25" at cradle) high, with scribed metal readout scale and applied Mylar labels. The housing contains a high torque motor with step-down gear mechanism attached to a machined stainless steel drive screw, speed selection/power switch and LED indicator lights. The power source is four AA alkaline batteries.

There are only minor configuration differences between the ViewCath™ Catheter Pullback and the predicate device. These minor differences do not alter the intended use or affect the safety and effectiveness of the ViewCath™ Catheter Pullback when used as labeled.

The intended use and the technological characteristics are the same as the predicate device and therefore we believe it is substantially equivalent to it.

Special Controls: Although there are no performance standards established by the FDA, or official industry standards for these devices, the ViewCath™ Catheter Pullback has been designed with FDA recommended development processes, within a Quality System including design and development procedures and manufactured in a GMP Quality System compliant facility.

Performance tests were conducted by testing the system to the requirements of the design specifications and comparison to the predicate devices.

The performance evaluations indicated that the system consistently performed within its design parameters, and equivalently to the predicate devices.

This data is summarized in the submission, and supports the safety and efficacy of the Quinton Imaging ViewCath™ Catheter Pullback.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Roy A. Smith
Manager of Manufacturing
Quinton Imaging Division
Quiton Instrument Company
1043 Kiel Court
Sunnyvale, California 94089

Re: K971397
ViewCath™ Catheter Pullback
Dated: July 30, 1997
Received: August 5, 1997
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

AUG 25 1997

Dear Mr. Smith:

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) 594-4613. 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/dsmamain.html".

Sincerely yours,

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

510(k) Number (if known): K 971397

Device Name: **ViewCath™ Catheter Pullback**

Indications For Use:

Statement of intended use:

The ViewCath™ Catheter Pullback is a device used for motorized pullback of medical Ultrasound intravascular imaging catheters to assist in consistent, selectable speed, 2-D image acquisition for use by medical imaging software for longitudinal view display or 3-D reconstruction and rendering and volumetric presentation of 3-D images for diagnostic review.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971397

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

(Optional Format 1-2-96)