K970669

AUG - 1 1997

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

Aeroquip Medical Products
2323 Green Road
Ann Arbor, MI 48105-1530
Contact Person: Ms. Christina L. Thomas, Medical Specialist

Date Summary Prepared: February 20, 1997

2. **Name of the Device:**

Aeroquip SafeStart™ IV Catheter

3. **Predicate Device Information:**

1) Critikon PROTECTIV™ manufactured by Critikon Inc.

2) Low Profile Safsite Y-Site manufactured by B. Braun.

4. **Device Description:**

The Aeroquip SafeStart™ IV Catheter device is a sterile, non-pyrogenic, disposable, peripheral vascular access catheter. The catheter check valve assembly consists of a catheter tube, a two-way internal check valve, a catheter body and a luer lock interface cap.

5. **Intended Use:**

The Aeroquip SafeStart™ IV Catheter is a sterile, non-pyrogenic, disposable peripheral vascular access catheter intended to provide peripheral venous access per CDC guidelines without the spillage of blood when accessing a vein or artery. It is intended to allow administration of drug and fluids into patients via a standard luer connection.

The Aeroquip SafeStart™ IV Catheter permits for any type of intravenous fluid administration (continuous and intermittent) or withdrawal of fluids.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 1997

Ms. Susan Goldstein-Falk
Official Correspondent
Aeroquip Medical Products
C/O MDI Consultants, Incorporated
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

Re: K970669
Trade Name: Aeroquip Safestart IV Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 6, 1997
Received: May 8, 1997

Dear Ms. Goldstein-Falk:

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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Aeroquip SafeStart™ IV Catheter

Indications For Use:

The Aeroquip SafeStart™ IV Catheter is a sterile, non-pyrogenic, disposable peripheral vascular access catheter intended to provide peripheral venous access per CDC guidelines hours without the spillage of blood when accessing a vein or artery. It is intended to allow administration of drugs and fluids into patients via a standard luer connection.

The Aeroquip SafeStart™ IV Catheter permits for any type of intravenous fluid administration (continuous and intermittent) or withdrawal of fluids.

(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)

(Optional Format 1-2-96)