OCT - 1 1997

15. Appendix F. 510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: Arlene Dutchik
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

510(k) Summary of Safety and Effectiveness

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: _____

Applicant Information:

Date Prepared: July 17, 1997
Name: ICU Medical, Inc.
Address: 951 Calle Amanecer
San Clemente, Ca 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

Device Information:

Trade Name: Intravascular Administration Set
Common Name: Core Resistant Huber Needle Sets
Classification Name: Intravascular Administration Set

Equivalent Device:

Micro Med/Core-Resistant Huber Infusion Set with and without Y-Site

Device Description:

The ICU Medical Core Resistant Huber Infusion Sets are single use, sterile and non pyrogenic devices intended for use as an accessory to deliver solutions and drugs into a patient's vascular implant port. Components used in the sets may be either manufactured by ICU Medical or purchased from approved contract manufacturers. Components will be assembled into standard configurations or configurations specified by the customer and packaged.

Intended Use:

The ICU Medical, Inc. Core Resistant Huber Needle Infusion Set, Core Resistant Huber Infusion Set with Y Site and Core Resistant Huber Infusion Set with Y Site and Clave are intended for use to deliver solutions and drugs through vascular implant ports.

Comparison To Predicate Device:

15.1. Comparative Information

CHARACTERISTIC COMPARED	ICU MEDICAL CORE RESISTANT HUBER INFUSION SET	MICRO MED, CORE RESISTANT HUBER NEEDLE INFUSION SET WITH OR WITHOUT Y SITE
Product Labeling	Sterile Use, Non Pyrogenic in unopened, undamaged, package. Directions for Use on label.	Sterile Use, Non Pyrogenic in unopened, undamaged, package.
Intended Use	Deliver solutions and drugs through vascular implant ports.	Deliver solutions and drugs through vascular implant ports.
Needle Gauges	19, 20, 22 gauge	19, 20, 22 gauge
Needle Lengths	½", ¾", 1", 1½"	½", ¾", 1", 1½"
Tubing Size	Macrobore and Minibore	Macrobore and Minibore
Color Coded Wings	Yes	Yes
Wing Assembly	Fixed	Fixed
CLAVE® Needleless Connector	Yes	No
Luer Lock	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 1997

Ms. Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K972712
Trade Name: Core resistant Huber Infusion Sets
Regulatory Class: II
Product Code: FPA
Dated: July 17, 1997
Received: July 21, 1997

Dear Ms. Dutchik:

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.

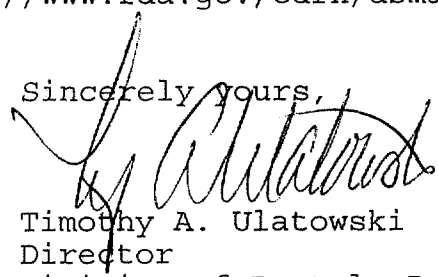
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

12. Appendix C. Indications for Use

The ICU Medical, Inc. Core Resistant Huber Infusion Set, Core Resistant Huber Infusion Set with Y Site and Core Resistant Huber Infusion Set with Y Site and CLAVE® are used to deliver solutions and drugs into vascular implant ports.

Rebecca Cucinotta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972712

Prescription Use ✓
(Per 21 CFR 801.109)