DEC 24 1998

10.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

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Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Sheryl Sáenz
Phone Number: (949)366-2183
Fax Number: (949)366-8368

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.

Applicant Information:

Date Prepared: October 7, 1998
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Sheryl Sáenz
Phone Number: (949) 366-2183
Fax Number: (949) 366-8368

Device Information:

Trade Name: Blood Tubing Accessory with CLAVE Connector
Common Name: Blood Access Accessory
Classification Name: Blood Access Device / Accessories

Equivalent Device:

MEDISYSTEMS ReadySet® Hemodialysis Blood Tubing Set, needle injection sites

Device Description:

The blood tubing accessory with CLAVE Connector is a single use, sterile, non-pyrogenic device intended for use as an adjunct to blood tubing sets or venipuncture devices for needle-free withdrawal of blood.

Intended Use:

The 'Blood Tubing Accessory with CLAVE Connector' is intended for use in hemodialysis and other chronic applications where blood sampling is required. Luer-locking adaptors allow secure, in-line placement between the blood tubing set and the catheter or venipuncture device. Use of a CLAVE connector allows the clinician needle-free blood withdrawal.

Comparison To Predicate Device:

Characteristic	ICU MEDICAL'S BLOOD TUBING ACCESSORY WITH CLAVE® CONNECTOR	Injection sites included on MEDISYSTEMS READYSET HEMODIALYSIS BLOOD TUBING SET
Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needle-free port to access any vein, or artery.	Needle injection sites on arterial and venous tubing sides for blood aspiration from tubing.
Design	One-piece connector activated by luer connection to allow blood withdrawal. Tubing and connectors are straight-line to minimize turbulence.	Pierceable septum secured in durable housing which is bonded to blood tubing set.
Materials	Y-Connector-Polyester Male Luer: Polypropylene Female Luer: Polyester Blood Tubing Extension: Polyvinylchloride CLAVE Connector: Polycarbonate, Polyester, Silicone, Fluorosilicone, Polypropylene, Polyethylene Packaging - Medical packaging grade fiber-free peelable paper lidding and pouching material.	Septum –Thermoplastic elastomer Housing – Polycarbonate Blood Tubing – Polyvinylchloride

Conclusions of nonclinical tests:

- Hemolysis study was conducted by independent laboratory and found that no significant hemolysis occurs with the use of the CLAVE Connector.
- Microbial challenge study showed that the CLAVE Connector maintained a sterile barrier for six days or 144 hours while administering 24 repeat activations per day. These results indicate that the CLAVE Connector, when using a standard disinfection protocol, did not increase infection rates under worst case clinical simulation.

Sheryl Sáenz
Regulatory Affairs Specialist
ICU Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 1998

Ms. Sheryl Saenz
Regulatory Affairs Specialist
ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673

Re: K983559
Blood Tubing Accessory with CLAVE® Connector
Dated: October 7, 1998
Received: October 13, 1998
Regulatory Class: II
21 CFR 876.5540/Procode: 78 FJK

Dear Ms. Saenz:

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, 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

Device Name: Blood Tubing Accessory with CLAVE Connector

INDICATIONS FOR USE

The 'Blood Tubing Accessory with CLAVE Connector' is intended for use in hemodialysis and other chronic applications where blood sampling is required. Luer-locking adaptors allow secure, in-line placement between the blood tubing set and the catheter or venipuncture device. Use of a CLAVE Connector allows the clinician needle-free blood withdrawal.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983559