K970855

17. Appendix H. 510(k) Summary of Safety and Effectiveness

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

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

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: K970855

Applicant Information:

Date Prepared: May 14, 199
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: Clave Connector
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set

Equivalent Device:

IVAC SmartSite™

Device Description:

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to Intravascular administration set.

Intended Use:

As an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

Comparison To Predicate Device:

Characteristic Compared	CLAVE® NEEDLELESS CONNECTOR	IVAC NEEDLE FREE VALVE ADMINISTRATION SETS (SMARTSITE™)
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	Needleless injection port to access any vein, or artery.	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silicone Rubber Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN 24 1997

Re: K970855
Trade Name: Clave Connector
Regulatory Class: II
Product Code: FPA
Dated: May 14, 1997
Received: May 19, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 at (301) 443-6597.

Sincerely yours,

Patricia Cucente /for

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 Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

(Division Sign-Off) Patricia Cucenta
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970855

Prescription Use ✓
(Per 21 CFR 801.109)