FEB 13 2008

K080077
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ICU MEDICAL INC.

4455 Atherton Drive
Salt Lake City, Utah
(801) 264 – 1332, Phone
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Tracy S. Best, Sr. Regulatory Affairs Specialist

Preparation Date: January 09, 2008

SPECIAL 510(K) Summary of Safety and Effectiveness for the:

Trade Name:	Clave® Stopcock
Common Name:	Accessory, Set, Administration, I.V.
Classification Name:	Set, Administration, Intravascular, 21 CFR 880.5440, Class II Device
Product Code:	Primary Code: FMG, Secondary Code: LHI

Legally Marketed Predicate Devices for Substantial Equivalence:

*K941190 – Clave Connector – ICU Medical, Inc.
*K970855 – Clave Connector – ICU Medical, Inc.
*K953573 – ICU Stopcock with Extension Tubing – ICU Medical, Inc.

Rationale for SE:

This submission is a combination of two devices that have been in the field for more than 15 years. These two devices are regarded highly within the industry and valued by our customers. This device will integrate the spike portion of the Clave into the molded portion of the Stopcock or the spike portion will function separately as it does now and be used as the base plug for the Stopcock portion. Then the other portions of the device remain the same as does the indications for use. There are no functional differences between any of the predicate devices or the proposed devices in terms of use.

Description of Submitted Device:

The Clave® Stopcock is a device that incorporates the functionality of needleless connectivity with the 4-way flow valve of a stopcock. The fluid path has three positions: Flush Position; Flow Position; and Port Access Position. The proprietary technology of the Clave enables the device to have a needleless port for administration of medications or other IV fluids as directed by the physician.

Intended Use:

The ICU Medical Clave Stopcock is a device used to administer or withdraw fluids that flow from a container to a patient's vascular system through a needle or catheter inserted into a vein or artery. This device is a four-way stopcock with an integral CLAVE side-port for closed, needleless access to the patient tubing or other fluid container.

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Technological Characteristics and Substantial Equivalence Table:

Component:	**ICU Medical, Inc. Clave Stopcock**	**ICU Medical, Inc. Clave**	**ICU Medical, Inc. Stopcock with ext. Tubing**
Stopcock Housing:	Polycarbonate		Polycarbonate
Stopcock Plug:	Polycarbonate		Polycarbonate
Stopcock Handle:	HD Polyethylene		Polyethylene & HDPE
Clave Body:	Valox	Valox	N/A
Clave Plug:	Silicone	Silicone	N/A
Clave Spike	Polycarbonate	Polycarbonate	N/A
Package:	Peel Blister pak	Peel Blister Pak	Peel Blister Pak
Sterilization method:	EtO or E-Beam	E-Beam	EtO or E-Beam
510(k) Approval	This submission	K941190 or K970855	K953573

The operational characteristics are identical as they have only changed to morph two devices together. Operation is the same for all Clave or Stopcocks, including the predicate devices.

Safety and Performance:

ICU Medical Clave Stopcock conform to the requirements of published international standards as well as those FDA recognized standards and/or published guidelines prior to marketing the device. Additionally, ICU Medical's Sterility Assurance Level, (SAL) has an established and validated history of meeting the 10^{-6} level. These devices will be packaged in a way as to ensure conformity with that SAL level. The manufacturing of these devices will be assembled in a quality environment that is certified independently and complies with cGMPs.

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate devices are substantially equivalent and safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2008

Mr. Tracy S. Best
Senior Regulatory Affairs Specialist
ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

Re: K080077
Trade/Device Name: ICU Medical Clave® Stopcock
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG, LHI
Dated: January 9, 2008
Received: January 15, 2008

Dear Mr. Best:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

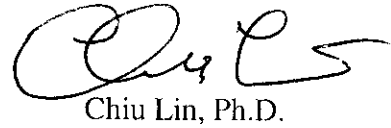
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name:

ICU Medical Clave® Stopcock

Indications for Use:

The ICU Medical Clave Stopcock is a device used to administer or withdraw fluids that flow from a container to a patient's vascular system through a needle or catheter inserted into a vein or artery. This device is a four-way stopcock with an integral CLAVE side-port for closed, needleless access to the patient tubing or other fluid container.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080077