ICU MEDICAL INC.
4455 Atherton Drive
Salt Lake City, Utah
(801) 264 – 1332, Phone
(801) 264 – 1755, Fax
Tracy S. Best, Sr. Regulatory Affairs Specialist
Preparation Date: April 04, 2008

K080989

ICU Medical, Inc.

MAY - 2 2008

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

Trade Name:	Universal Vial Access Device
Common Name:	Accessory to Piston Syringe, Needleless
Classification Name:	Piston Syringe, Accessory 21 CFR 880.5860, Class II Device
Product Code:	FMF

Legally Marketed Predicate Devices for Substantial Equivalence:

*K934561 – One Time Vial Access – ICU Medical, Inc.
*K934591 – Clave Vial Access Spike – ICU Medical, Inc.

Rationale for SE:

These combo device is the vial access spike and the proprietary Clave® needleless access device. This device integrates the spike portion and the Clave with an improved clip that can adapt to all sizes of drug vials. A hydrophobic filter ensures airborne contaminates larger than 0.2μm. There are no functional differences between any of the predicate devices or the proposed devices in terms of use.

Description of Submitted Device:

The ICU Medical Universal Vial Access Device is a single use – universally adaptable and needleless drug container access disposable. The proprietary technology of the Clave enables the device to have a needleless port for withdrawal of medications or other IV fluids as directed by the physician.

Intended Use:

Accessory to a piston syringe for needleless access to sterile drug vials without the use of needles.

Safety and Performance:

ICU Medical Universal Vial Access Device 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 are 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

MAY - 2 2008

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

Re: K080989
Trade/Device Name: ICU Medical Universal Vial Access Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 4, 2008
Received: April 7, 2008

Dear Ms. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K080989

Device Name:

ICU Medical Universal Vial Access Device

Indications for Use:

Accessory to a piston syringe for needleless access to sterile drug vials without the use of needles.

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: K080989