ICU MEDICAL INC.

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Mr. Tracy S. Best, Sr. Regulatory Affairs Specialist

Preparation Date: May 06, 2008

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

Trade Name: Graduated Adapter with Clave®

Common Name: Needless connector with graduated adapter

Classification Name: Accessory to Urological Catheter 21 CFR 876.5130 (EZD)

Legally Marketed Predicate Devices for Substantial Equivalence:

*K915571 – Clave Connector – ICU Medical Inc.
*K970855 – Clave Connector – ICU Medical, Inc.
*K941190 – Clave Needless Connector – ICU Medical, Inc.
*K964435 – Primary IV Set – ICU Medical, Inc.
*K042182 – Y-Clave Connector with Integrated Check Valve – ICU Medical, Inc.
*K041464 – Urethral Catheter and Urine Catheter Kit – Busse Hospital Disposables

Rationale for SE:

The Clave is a needless adapter that is used individually or in combination with other devices more than 6 million times annually around the world. The adaption of a graduated adapter is new to the clave, but accessories integrated with the Clave to make patient care easier for the caregiver is not new concept. As shown in K964435 and K941190, these submissions included adaptors for different purposes to use the Clave that fall outside the original intended use as defined in K915571. I.V. Sets and various componentry integrated the use of the Clave as requested by the physician and as needed for better patient care. ICU Medical is a custom kit manufacturer in the disposable infusion therapy market. The Graduated Adapter with Clave has been developed for the same purpose; to help make the caregiver's job easier and to simplify patient care by providing this presterilized device for those physicians that use them. The Urine Catheter Kit from Busse (K041464) is an example of how companies develop different kits for physicians for the care of patients.

Description of Submitted Device:

The Clave with Graduated Adapter is a device that allows the Urologist a device that can "slip-fit" on a urology catheter. This is then used to infuse fluids into the bladder for procedures as the physician determines. The Clave can connect to a threaded device or any ISO 594-1 & -2 compliant luer device. When the Clave is activated, fluid may then pass through the graduated adapter. When the syringe or luer is disconnected, the Clave can withstand back pressures as much as 45 psi and thereby preclude fluid leakage coming from the bladder via the catheter and attachment.

The submitted device consists of a Clave which has a spike, stepped silicone plug and body that is then solvent-bonded to a graduated adapter using cyclohexanone, dichloride or validated equivalent.

Intended Uses of the ICU Medical Syringe:

ICU Medical Graduated Adapter with Clave® is indicated as an accessory to a urinary catheter which facilitates the transfer of fluids into or out of the bladder via connection to the graduated adapter. This device for single procedure use only. Connection to catheter not to exceed 30 days.

Technological Characteristics and Substantial Equivalence Table:

Component:	**ICU Medical Graduated Adapt. with Clave**	**ICU Medical Clave Needless Connector**	**Urine Catheter Kit by Busse Hospital Disposables**
Spike Body:	ABS or Cyrex	ABS or Cyrex	N/A
Stepped Silicone Plug	LSR – Liquid Silicone Rubber	LSR – Liquid Silicone Rubber	N/A
Body:	Polyester	Polyester	N/A
Graduated Adapter	Polycarbonate	N/A	Polypropylene connectors, PVC catheters, Polycarbonate specimen containers
Sterilization method:	Gamma / E-Beam	Gamma / E-Beam	Gamma or ETO
Other component:	N/A	Various: polycarbonate, PVC, polypropylene, ABS, Cyrex & more	PVC catheter, etc.
510(k) Approval	This submission	K915571; K970855; K941190; K964435; K045182	K041464

The operational characteristics are equivalent; by manually inserting the graduated adapter into the open end of the catheter, then connecting the Clave to a syringe or an ISO 594-1; -2 compliant Luer to allow the physician to infuse or withdraw fluids.

Safety and Performance:

ICU Medical complies with published international standards to ensure the commonality of connecting components. All standards complied with are listed in the CDRH Cover Sheet. Additionally, ICU Medical's Sterility Assurance Level, (SAL) has an established and validated history of meeting the 10^{-6} level. This single use Graduated Adapter with Clave are packaged to ensure conformity with ISO 10993-1 for biocompatible materials and ISO 11137-1 for sterilization by radiation.

Conclusion:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 13 2008

Mr. Tracy Best
Sr. Regulatory Affairs Specialist
ICU Medical, Incorporated
4455 Atherton Drive
SALT LAKE CITY UT 84123

Re: K080007
Trade/Device Name: Graduated Adapter with Clave®
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD and KNY
Dated: April 4, 2008
Received: April 7, 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 (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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080007

Device Name: Graduated Adapter with Clave®

Indications for Use:

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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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K080007