

## ICU MEDICAL INC.

4455 Atherton Drive  
Salt Lake City, Utah  
(801) 264 – 1332, Phone  
(801) 264 – 1755, Fax  
Mr. Tracy S. Best, Sr. Regulatory Affairs Specialist  
Preparation Date: August 26<sup>th</sup> 2008



1081361

**ICU Medical, Inc.**

**AUG 28 2008**

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

**Trade Name:** ChemoCLAVE<sup>®</sup> Cytotoxic Medication Preparation and Delivery System  
**Common Name:** Chemotherapy I.V. Preparation, Transfer and Administration Sets  
**Classification Name:** Set, I.V. Fluid Transfer & Set, Administration, Intravascular  
21 CFR 880.5440, Class II Device  
**Product Codes:** Primary Code – LHI, Secondary Code – FPA

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### **Legally Marketed Predicate Devices for Substantial Equivalence:**

*Clave Connector – K970855	*Chemo Dispensing Pin – K024239
*Genie <sup>™</sup> – K070633	*Chemo-AIDE – K003730
*Clave Vial Access Spike – K934591	*Taxol Administration Set – K003513
*Spiros <sup>™</sup> – K070532	*Chemo Spike II Reconstitution Device – K974431
*Universal Vial Access Spike – K080989	
*Primary IV Set – K964435	
*Single Use Syringe – K070856	

### **Rationale for SE:**

The ChemoCLAVE Cytotoxic Medication Preparation and Delivery Systems are a combination of ICU Medical devices that are already legally marketed around the world. In short, we are incorporating these previously cleared devices to withdraw cytotoxic agents from a vial for transfer to the administration set and finally, to the patient. All of the predicate devices listed above left are part of this submission.

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### **Description of Submitted Device:**

The ChemoCLAVE Cytotoxic Medication Preparation and Delivery System is a combination of ICU Medical's products and tested for compatibility with lipids and/or cytotoxic agents. The "System" part is where these devices are packaged individually or sold together as a custom set upon order of the physician for the purpose of enabling the user a safe and inexpensive alternative to other passively closed systems. The predicate devices have been successfully used in the practice of administration of chemotherapy agents to patients for many years. In this submission, we are specifically requesting to market the name "ChemoCLAVE Cytotoxic Medication Preparation and Delivery System."

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### **Intended Use:**

The ChemoCLAVE Cytotoxic Medication Preparation and Delivery System consists of 6 previously cleared components (CLAVE<sup>®</sup>, Spikes, SPIROS<sup>™</sup>, GENIE<sup>™</sup>, Vial Access, and Admin Sets) that can be combined into various configurations intended for use in the preparation and patient administration of cytotoxic medications.

**Technological Characteristics and Substantial Equivalence Table:**

<b><u>Device:</u></b>	<b>CLAVE®</b>	<b>SPIKES</b>	<b>SPIROS™</b>	<b>GENIE™</b>	<b>VIAL ACCESS</b>	<b>ADMIN SETS</b>
The ChemoCLAVE Cytotoxic Medication Preparation and Delivery System is any combination of these already approved & marketed devices.	Same design, materials, assembly	Purchased and qualified component	Same design, materials, & assembly	Same design, materials, & assembly	Materials & assembly similar	Same design and materials and assembly
	Needleless	Needleless	Needleless	Needleless	Needleless	N/A
	Passively closed	N/A	Passively Closed	Passively Closed	N/A	N/A
	Gamma	Gamma	Gamma	Gamma	Gamma	Gamma
	K970855	K964435 & OEM	K070532	K070633	K934591; K934561 & K080989	K964435 & OEM
Some of the Catalog codes	C1000; B3300; CH3000; etc.	CH-12; CH-13; CH-14; CH-15; etc.	CH2000; CH3000; etc.	CH-77; etc. (vial size)	CH-10; CH-50; CH-51; CH-52; CH-55; CH-60; CH-70; etc. (vial size)	Too numerous to list ( due to tubing length & accessories)

**Safety and Performance:**

ICU Medical conforms to international standards in the design, development, and manufacturing of all of their unique disposable medical devices. Additionally, ICU Medical's Sterility Assurance Level, (SAL) has an established and validated history of meeting a 10<sup>-6</sup> level. The single use ChemoCLAVE Cytotoxic Medication Preparation and Delivery System components are packaged in blister packs with Tyvek lidding.

**Conclusion:**

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 28 2008

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

Re: K081361  
Trade/Device Name: ChemoCLAVE® Cytotoxic Medication Preparation and  
Delivery System  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: II  
Product Code: FPA, LHI  
Dated: August 21, 2008  
Received: August 22, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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,



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): **K081361**

Device Name: **ChemoCLAVE® Cytotoxic Medication Preparation and Delivery System:**

Indications for Use:

The ChemoCLAVE Cytotoxic Medication Preparation and Delivery System consists of 6 previously cleared components (CLAVE®, Spikes, SPIROS™, GENIE™, Vial Access, and Admin Sets) that can be combined into various configurations intended for use in the preparation and patient administration of cytotoxic medications.

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)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

*Anthony D. ...*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: **K081361**