K090189
1 of 2

ICU MEDICAL INC.
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Tracy S. Best, Sr. Regulatory Affairs Specialist
Preparation Date: 04/09/2009

ICU Medical, Inc.

APR 10 2009

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

Trade Name: Antimicrobial CLAVE, Ag CLAVE®

Common Name: Needleless Connector, Needlefree Connector, Closed Access

Classification Name: 21 CFR 880.5440, Class II Device, 80FPA and 80LHI, Accessory

Legally Marketed Predicate Devices for Substantial Equivalence:

*K970855 – CLAVE Connector – ICU Medical Inc.
*K072576 & K081289 – V-Link™ Antimicrobial Luer Activated Device – Baxter Healthcare Corp

Rationale for SE:

The ICU Medical Antimicrobial CLAVE is equivalent to devices that provide a needleless connection with a closed system. The antimicrobial feature is substantially equivalent to those devices already approved as they release antimicrobial ionic silver. The components of the Antimicrobial CLAVE are molded from materials that are identical to or substantially equivalent to its predicate, the CLAVE Connector. The V-Link is a needleless connector as is the submitted device. Both the CLAVE and the V-Link have a proven history in the medical device market. While V-Link uses a silver coating, the ICU Medical Ag CLAVE components are compounded with the antimicrobial agents to prevent the agent from wearing off the components.

Description of Submitted Device:

The ICU Medical Ag CLAVE is created with two different and effective antimicrobial agents. The first antimicrobial agent, compounded with the liquid silicone rubber (LSR), then molded into the plug that seals around and protects the fluid path is the first line of defense. The second antimicrobial agent, compounded with the plastics used to mold the cannula protects the fluid path from bacteria growth. Both the plug material and the cannula material are identical to the traditional CLAVE Connector as described in K970855 before the antimicrobial agents are compounded with them. Both the submitted and predicate CLAVE device are made up of three components; an internal plastic cannula (spike) which incorporates the fluid path, a plastic housing which allows for standardized ISO 594-1/2 luer lock connections and a silicone septum (plug) which provides the sealing mechanism and swabbing surface.

Efficacy and functional testing of the device are included in this submission. Additionally, the Antimicrobial CLAVE has been tested under the ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing.* The results of that testing is included in this submission.

K090189
2 of 2

Intended Use of the Antimicrobial CLAVE:

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

The connector includes two antimicrobial agents. The first agent is compounded with liquid silicone rubber to provide a protective seal around the cannula. The second agent is compounded with the polycarbonate alloy and is intended to reduce microbial contamination in the device fluid path. The antimicrobial agents are not intended for treating existing patient infections.

Technological Characteristics and Substantial Equivalence Table:

Component:	ICU Medical Ag CLAVE	ICU Medical CLAVE Connector	Baxter Healthcare V-Link
Treated components	1. Liquid Silicone Rubber 2. Cannula/Spike/Fluid path	None	All surfaces of the polycarbonate device
Antimicrobial Agent & application	1. AM Agent Compounded - LSR 2. AM Agent Compounded - Polycarbonate Alloy	None None	Antimicrobial Coating
Sterilization Method	Gamma or E-beam	Gamma or E-beam	Gamma
510(k) Approval	This submission	K970855	K072576 and K081289

The operational characteristics are identical to predicate devices for needleless luer connection.

Safety and Performance:

ICU Medical Antimicrobial CLAVE's are accessories and not a standalone device. Additionally, ICU Medical performs risk analysis and design verification testing based on pre-determined criteria published internally as a Performance Specification and based on ISO 14971. All tests meet the performance specification defined for the Antimicrobial CLAVE Connector.

ICU Medical has also performed testing recommended by the draft guidance "*Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents*" and has included that testing as part of this submission.

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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Salt Lake City, Utah 84123

APR 10 2009

Re: K090189
Trade/Device Name: Antimicrobial CLAVE
Regulation Number: 21 CFR 880.5440
Regulatory Class: II
Product Code: FPA, LHI

Dated: January 23, 2009
Received: January 26, 2009

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Anthony D. Watson for
Susan Runner, D.D.S., MA
Acting 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): K090189

Device Name: Antimicrobial CLAVE

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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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090189