K021692

DEC - 4 2003

3. A revision of the Summary of S&E with the correct name and indication/intended use,

510(K) Summary

Name: ICU Medical, Inc.
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San Clemente, CA 92673
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510(K) Summary of Safety and Effectiveness

The summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is: K021692
Trade Name: CLC2000® Catheter Patency Device
Common Name: Accessory, Intravenous Administration Device
Classification Name: Same

Equivalent Device: ICU Medical CLC2000 (K973167)
B.Braun Safsite® (510(K) number unknown)

Device Description:

The CLC2000 is a swab-able normally closed two-way luer activated valve. Within the housing of CLC2000, is a spring-loaded poppet whose head protrudes out of the female luer of the device. The poppet has an outer diameter that is smaller than the inner diameter of the housing. O-rings are positioned at the head and base of the poppet and form a physical seal between the poppet and the inner wall of the housing. A male luer with a rotating collar protrudes from the housing.

The fluid pathway is opened when a male luer taper engages the female luer on the device. The male luer will push the poppet and the O-rings from their normally closed positions. The inner wall of the housing opens up at a point below the rest position of the top O-ring. When the top O-ring passes this point, it looses contact with the inner wall of the housing allowing fluid to flow freely to the male luer. The device at this stage is considered in the "open position". With the device in the open position, fluids can be injected or withdrawn. The bottom O-ring maintains contact with the inner wall of the housing at all times preventing fluid from flowing past the bottom O-ring. Once the luer taper is removed from the device, the spring-loaded poppet and O-rings are allowed to return to the "closed position". As the O-rings slide back up, the fluid trapped between the O-rings is forced out through the male luer, creating a positive displacement of fluid. This displacement of fluid prevents blood from being drawn into the lumen of the catheter when the male luer is removed from the device.

Intended Use:

The CLC2000 is intended for use as an accessory to a vascular access device. The CLC2000 will reduce thrombotic occlusion within the internal catheter lumen and fibrin formation. The CLC2000 is designed to assist in maintaining catheter patency. The CLC2000 does not require the use of needles and therefore will passively aid in the reduction of needlestick injuries.

Biocompatibility:

The patient contacting materials used to manufacture the CLC2000 meet ISO 10993 for External Communicating Devices, Blood Path Indirect, Prolonged Contact Duration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Ms. Alison Burcar
Regulatory Affairs
IUC Medical, Incorporated
951Calle Amanecer
San Clemente, California 92673

Re: K021692
Trade/Device Name: CLC2000 Catheter Patency Device
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 5, 2003
Received: September 8, 2003

Dear Mr. Burcar

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 (301) 594-4618. 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/dsma/dsmamain.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

K021692

Indications for Use

510(k) Number (if known): K021692

Device Name: CLC2000®

Indications For Use:

The CLC2000 is intended for use as an accessory to a vascular access device. The CLC2000 has been shown to reduce thrombotic occlusion within the internal catheter lumen and fibrin formation in an animal study. The CLC2000 is designed to assist in maintaining catheter patency. The CLC2000 does not require the use of needles and therefore will passively aid in the reduction of needlestick injuries.

Susan Runo

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

510(k) Number: K021692

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