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16. **Appendix F. 510(k) Summary of Safety and Effectiveness**

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: **ICU Medical, Inc.**
Address: **951 Calle Amanecer**
San Clemente, CA 92673

Contact Person: Salvadore F. Palomares
Phone Number: (714)366-2183
Fax Number: (714)366-8368

510(k) Summary of Safety and Effectiveness

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

Device Information:
Trade Name: SmartValve
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set

Equivalent Device:
McGaw Anesthesia Triple Valve Manifold
ICU Medical Stopcock with Extension Tubing

Device Description:
The SmartValve is a single use, sterile, non-pyrogenic pressure activated valve intended for use as an accessory to Intravascular administration set.

Intended Use:
The SmartValve is a single use, sterile, non-pyrogenic pressure activated check valve system intended for use as an accessory to Intravascular administration set. The SmartValve provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein or artery). The SmartValve also provides access for the withdrawal of fluids from administration set.

Biocompatibility:
The materials used to manufacture the SmartValve are used in legally marketed devices under comparable conditions of use.

Salvadore F. Palomares
Manager of Regulatory Affairs
ICU Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Salvadore F. Palomares
Manager of Regulatory Affairs
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K974589
Trade Name: Smartvalve
Regulatory Class: II
Product Code: FPA
Dated: December 8, 1997
Received: December 9, 1997

Dear Mr. Palomares:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

14. **Appendix D. Indications for Use**

510(k) Number (if known):

Device Name: SmartValve

Indications For Use:

The SmartValve is a single use, sterile, non-pyrogenic pressure activated check valve system intended for use as an accessory to Intravascular administration set. The SmartValve provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein or artery). The SmartValve also provides access for the withdrawal of fluids from administration set.

(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 Dental, Infection Control, and General Hospital Devices
510(k) Number K974589

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)