K011888

SEP 1 0 2001

510(K) Summary

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

1.	Submitter: Address: Phone: Fax: Contact:	Churchill Medical Systems, Inc. 87 Venture Drive Dover, NH 03820 603-743-5988 603-743-6328 Keith Paluch (Consultant)
2.	Device Name: Trade Name: Classification Name:	Check Valve Accessory Pressure Activated Check Valve IV Administration Set
3.	Classification:	Class II, General Hospital 80 FPA
4.	Predicate Device:	KVO Check Valve Accessory (K98441)
5.	Device Description:	The Churchill Medical Systems Pressure Activated Check Valve consists of acrylic-polycarbonate alloy valve body and a silicone valve with male and female luer lock connections. The device opens at cracking pressures of greater than 3.5 PSI +/- 1 PSI and prevents back flow.
6.	Intended Use:	This device is used to directionally control the flow of fluids. They are added to IV cannula or extension sets for simultaneous or alternate administration of fluids while preventing back flow of medication.
7.	Performance Summary:	This device is manufactured and tested in accordance with physical, chemical and biological specification conforming to the applicable requirements set forth in ISO 10993, USPXX111, ISO 11607-1, ISO 11135, USP Pyrogenicity test requirements as well as documented internal requirements for physical testing.
8.	Conclusion:	This device shares similar technical characteristics to check valves currently available in the marketplace. Specifically, this device performs similarly to the predicate device, referred to as KVO Check Valve Accessory (K984441). Testing summary results confirm this device to be safe and effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2001

Mr. Keith Paluch
Consultant
Churchill Medical Systems, Incorporated
87 Venture Drive
Dover, New Hampshire 03820

Re: K011888
Trade/Device Name: Pressure Activated Check Valve
Regulation Number: 21 CFR 880.5440
Regulation Name: Check Valve Accessory
Regulatory Class: Class II
Product Code: FPA
Dated: July 24, 2001
Received: August 2, 2001

Dear Mr. Paluch:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

510(k) number K011888

Device Name: Pressure Activated Check Valve

Indications for Use: Accessory device used to allow pressurized fluid flow in one direction and stop, or check flow in the opposite direction.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use___
(Per 21CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K011888