K013949

510(K) Summary

MAR 2 7 2002

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:	Vial Access Device Universal Vial Access Spike with Needleless Connector IV Set Stopcock, IV Administration Set Accessories
3.	Classification:	Class II, General Hospital 80 FPA
4.	Predicate Device:	B-D Blunt Plastic Cannula 510(k) 974363
5.	Device Description:	The Churchill Medical Systems vial access device is a sterile, single use, one piece shrouded plastic cannula designed to penetrate septums covering plastic or glass medication vials. The device is intended to be marketed with and without needleless connector port permanently attached.
6.	Intended Use:	This device is used to replace hypodermic needles used to pierce and withdraw medical fluids from plastic and glass vials. Use of this device prevents accidental needle sticks in this application.
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 the B-D Blunt Plastic Cannula in that both devices guard against accidental needle sticks caused by human contact with sharp surfaces. 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

MAR 2 7 2002

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

Re: K013949
Trade/Device Name: Churchill Medical Systems Vial Access Spike with Needleless Connector
Regulation Number: Intravascular Administration Set and Hypodermic Single Lumen Needle
Regulation Name: 880.5440 and 880.5570
Regulatory Class: II
Product Code: LHI and FMI
Dated: January 19, 2002
Received: January 28, 2002

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.

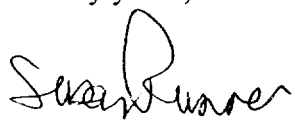
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

Indications For Use

510(k) Number (if known): K013949

Device Name: Churchill Medical Systems Vial Access Spike with Needleless Connector

Indications For Use:

Churchill Medical Systems Vial Access Spike with Needleless Connector is used in I.V. therapy to pierce glass and plastic stopper top vials for the transfer of medical fluids. This device eliminates the use of metal hypodermic needles to reduce the chance of inadvertent needle sticks.

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

Prescription Use_____ **Or** **Over-The-Counter Use**_____

Patricia Cucante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013949