K971500

AUG 18 1997

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# 510(k) Summary

Re: Trade Name: Access Systems Needleless Vial Adapter
Common Name: Needleless Vial Access Device
Classification Name: Tubes,Vials,Systems,Serum Separators, Blood Collection 75JKA

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 and DSMA 1995.

The B.E.C. Needleless Vial Adater consists of a Needleless Injection Site which is a tubular body with a male luer slip attachment at one end. This site is bonded to the female luer lock of the Medimop Vial Access device. The other end of the injection sites tubular body is provided with an enlarged section adapted to receive a cylindrical retaining ring which surrounds and compresses a pre-slit, natural rubber or polyisoprene septum. The septum retaining ring and enlarged section of the tubular body are adapted to receive and latch with the BEC, MED-NET or IMED shrouded plastic cannula. The pre-slit septum re-seals upon removal of the cannula.

The Needleless Injection Site is intended to provide additional protection against inadvertent "needlestick" injuries to health care providers during the administration of fluids and medications. The Needleless Vial Adapter provides for the entry into a stoppered vial without the need of a sharp needle by allowing for the use of a blunt cannula.

This needleless vial adapter is similar to those marketed by Baxter Healthcare, Abbott Laboratories, and McGaw, Inc. Technological data and performance data for the injection site employed were submitted for the IMED predicate device in 510(k) #K944320.

## 510(k) Summary (Continued)

Packaging of the device is either performed in-house or under contract by a registered device establishment. Sterilization is performed in-house using a validated ethylene oxide process. Both packaging and sterilization procedures are consistent with those generally used by the medical device industry.

Contact Person: James P. Kulla, President

4/22/97
Date Prepared

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1997

Mr. James P. Kulla
President
Biological & Environmental Control Laboratories
705 Front Street
Toledo, Ohio 43605

Re: K971500
Trade Name: Access Systems Needleless Vial Adapter
Regulatory Class: II
Product Code: FPA
Dated: August 1, 1997
Received: August 4, 1997

Dear Mr. Kulla:

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

510(k) Number (if known): K971500

Device Name: Needleless Vial Adapter

Indications For Use:

The risk to health care providers of "needlestick" injuries has become a major public health and worker safety concern. The Needleless Vial Adapter is intended to provide additional protection against inadvertent "needlestick" injuries to health care providers during the administration of fluids and medications. The Needleless Vial Adapter provides for the entry into a stoppered vial without the need of a sharp needle by allowing for the use of a blunt cannula.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Adriana Cruzeta

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

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

(Optional Format 1-2-96)