

The Medi-Dose® Group

K974431

PRODUCTS AND SYSTEMS FOR THE HEALTH CARE COMPLEX

Medi-Dose® Inc.

EPS® Inc.

EXTEM-PREP™ SYSTEMS

Vu-Pak® Systems

Mailing Unlimited

Summary of Safety and Effectiveness

JAN - 8 1998

Name of Device: Chemo-Spike® II Reconstitution Device

Catalog Number: IV5002

Classification: Chemo Dispensing/Mixing accessories would most likely have been reviewed by the FDA General Hospital Panel, Code 80, product code assignment 80FMF. This product would most likely be categorized as an accessory to a syringe, according to 21 CFR 880.5860.

Summary Statement

The Chemo-Spike II Reconstitution Devices has been designed for preparing and dispensing lyophilized chemotherapy drugs in vials. The device offers a sterile vent pathway, filtering the air, as well as a filtered pathway for the actual diluent or medication. The sterile vent protects the health care practitioner by releasing the vacuum from the drug vials during reconstitution with diluent. It also protects the patient by filtering microprecipitates and crystallizations. from the diluent after reconstitution.

The Chemo-Spike II Reconstitution Device consists of 2 filter media, a 5 micron hydrophilic filter for the actual medication (i.e. fluid) pathway and a 0.2 micron hydrophobic filter for venting the air pathway. Both filters are manufactured from PTFE (polytetrafluoroethylene) membrane and are housed in molded acrylic. The effective filtration area for the medication measures 1.0 cm² while the effective vent area measures 4.0 cm². USP Class VI Plastics testing has been conducted on the device and has been found to be biosafe.

The Chemo-Spike II Reconstitution Device is the predicate device granted 510(k) #K941020, manufactured by Gelman Sciences, Inc. Gelman Sciences, Inc. is the actual subcontractor of this product. The Chemo-Spike II Reconstitution Device is to be used in exactly the same manner as the predicate devices and introduces no new issues of safety and effectiveness.

1785 Stout Drive, Warwick, PA 18974-6101

PHONE: 800-523-8966 1.215.956.9900

FAX: 800-323-8966 1.215.956.9955

WEB SITE: <http://www.medi-dose.com> E-MAIL: info@medi-dose.com

The Medi-Dose® Group

K974431

PRODUCTS AND SYSTEMS FOR THE HEALTH CARE COMPLEX

Medi-Dose® Inc.

EPS® Inc.

EXTEM-PREP™ SYSTEMS

Vu-Pak® Systems

Mailing Unlimited

Summary of Safety and Effectiveness

Name of Device: Dispensing-Spike II Device

Catalog Number: IV2052

Classification: I.V. Dispensing/Mixing accessories would most likely have been reviewed by the FDA General Hospital Panel, Code 80, product code assignment 80FMF. This product would most likely be categorized as an accessory to a syringe, according to 21 CFR 880.5860.

Summary Statement

The Dispensing-Spike II has been designed for preparing and dispensing multiple dose I.V. medication stored in rubber-stoppered vials. It is equipped with a sharp piercing spike and tight luer lock port with a hinged cap. The technician pierces the medication vial just once with the spike. A syringe, without a needle, should be affixed to the luer lock port. Repetitive injections into or aspirations from the multiple dose I.V. vial are made through the port of the spike device. This reduces the number of times the diaphragm of the vial is pierced.

The Dispensing-Spike II is equipped with a 0.2 micron polytetrafluoroethylene (PTFE) hydrophobic filter for venting the air pathway. The sterile vent protects the health care practitioner by helping to release the vacuum from the drug vials during reconstitution with diluent.

The Dispensing-Spike II is manufactured from PTFE (mentioned above) and molded acrylic. The effective filtration area measures 1.0 cm². USP Class VI Plastics testing has been conducted on the device and has been found to be biosafe.

Please note that this product has been granted 510(k) #K946190 to Gelman Sciences, Inc. of Ann Arbor, MI. Gelman Sciences is the actual subcontractor of this product. The only change between the Gelman Sciences product and the EPS product described above is the method of sterilization and packaging.

The Dispensing-Spike II Device is the predicate device granted 510(k) #K946190, manufactured by Gelman Sciences, Inc. Gelman Sciences, Inc. is the actual subcontractor of this product. The Dispensing-Spike Device is to be used in exactly the same manner as the predicate devices and introduces no new issues of safety and effectiveness.

1785 Stout Drive, Warwick, PA 18974-6101

PHONE: 800-523-8966 1.215.956.9900

FAX: 800-323-8966 1.215.956.9955

WEB SITE: <http://www.medi-dose.com> E-MAIL: info@medi-dose.com



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Braverman
Director of Marketing
Medi-Dose, Incorporated
1671 Loretta Avenue
Feasterville, Pennsylvania 19053

JAN - 8 1998

Re: K974431
Trade Name: Chemo-Spike II Reconstitution Device
Regulatory Class: II
Product Code: LHI
Dated: November 22, 1997
Received: November 24, 1997

Dear Mr. Braverman:

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.

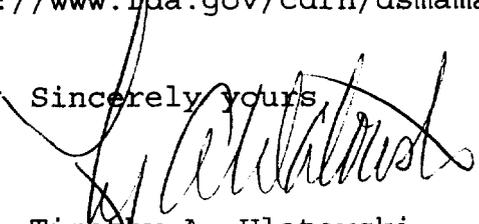
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K974431

Device Name: CHEMO-SPIKE II RECONSTITUTION DEVICE

Indications For Use: DISPENSING SPIKE II DEVICE

Indication for Use of Chemo-Spike® II Reconstitution Device

The Chemo-Spike II Reconstitution Device is indicated for use in the preparation and dispensing of lyophilized chemotherapy drugs in multiple dose vials. The device is used to either add diluent to the vial or to withdraw medication from the vial. These medications and devices should be used by hospital medical personnel properly trained in aseptic procedures. The Chemo-Spike II Reconstitution Device is indicated for use prior to patient administration or physician use.

Indication for Use of Dispensing-Spike II Device

The Dispensing-Spike II Device is indicated for use in the preparation and dispensing of IV medication from multiple dose IV vials. The device is used to either add diluent to the vial or to withdraw medication from the vial. These medications and devices should be used by hospital medical personnel skilled and trained in maintaining aseptic technique. The Dispensing-Spike II is indicated for use prior to patient administration or physician use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Caserta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974431

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use