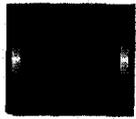


K971004



OCT - 2 1997

25612 Stratford
Laguna Hills, CA 92653 USA
Telephone: 714.582.0313 FAX: 714.582.3747

Attachment 1

**510(k) Summary
Medcorp Flow I.V. Regulator Extension Set**

Name and Address: Medcorp International
25612 Stratford Place
Laguna Hills, CA 92653

Contact Person: Dave Berberian
Phone: (714) 582-0313
Fax: (714) 582-3747

Date Prepared: March 1, 1997

Tradename Name: Medcorp Flow I.V. Regulator Extension Set
Common Name: I.V. Extension Set
Classification Name: Intravascular Administration Set (per 21 CFR 880.5440)

Classification Name: Intravascular Administration Set

Predicate Device: DIAL-A-FLOW Regulatory I.V. Extension Set

Description: The device is a sterile, nonpyrogenic, single use, I.V. extension set which has flexible tubing that connects to a fluid delivery system by a Luer lock connector, a flow regulator, and flexible tubing that connects to a venipuncture device by a Luer lock connector. A Y-site on the lower length of tubing allows for infusion of medication below the regulator.

Indicated Use: To provide fluid path connection and flow regulation from fluid delivery set to venipuncture device.

Substantial Equivalence: Medcorp International believes that the Medcorp Flow I.V. Regulator Extension Set is substantially equivalent to the DIAL-A-FLO Regulator I.V. Extension Set in intended use, labeling, design, components, performance, and biocompatibility. To establish the claim of equivalence to the predicate device, physical testing (flow rates and static tensile strength of fittings), toxicity testing, and pyrogenicity testing) have been performed using the device. The flow rates for the device are equivalent to those indicated by the calibrations for the predicate device. The toxicity testing indicate the device, after manufacturing and sterilization, is nontoxic. Pyrogenicity testing supports the claim for the device which is the same as the claim for the predicate device. Tests support the claim that the proposed device is equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 2 1997

Mr. Dave Berberian
President
Medcorp International
25612 Stratford
Laguna Niguel, California 92653

Re: K971004
Trade Name: Medcorp Flow I.V. Regulator Extension Set
Regulatory Class: II
Product Code: FPA
Dated: July 29, 1997
Received: August 1, 1997

Dear Mr. Berberian:

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

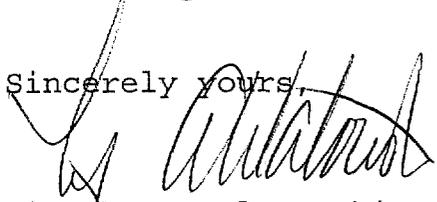
Page 2 - Mr. Berberian

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

K 971004

510(k) Number (if known): _____

Device Name: Medcorp Flow I.V. Regulator Extension Set

Indications For Use:

To provide fluid path connection and flow regulation from fluid delivery set to venipuncture device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Ciccone
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 971004

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____