

JUL 21 1998

K982123

510 (k) Summary

This summary regarding 510(k) safety and effectiveness and being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 807.92.

807.92(a)(1) Submitter's (and Contact) Name, Address, Telephone No., Summary Date

Cathy Chenetski
Director, Regulatory Affairs
Medex
3637 Lacon Road
Hilliard, OH 43026
(614) 529-3932

June 11, 1998

807.92(a)(2) Device Name (Including Trade Name), Common Name, Classification Name

Classification Name: Intravascular Administration Set (80 FPA)
Common/Usual Name: Intravascular Fluid Delivery Set
Trade/Propriety Name: Not yet determined.
Part Number: Not yet determined

807.92(a)(3) Legally Marketed Predicate Device to Which Equivalence is Claimed

The modified Contrast Control Device, for purposes as defined under Section 510(k) of the Federal Food, Drug and Cosmetic Act, are substantially equivalent to the Medex IV Administration Set, K883318 and pre-amendment (primary predicate). Additionally, the Contrast Control Device is substantially equivalent to the Namic Contrast Savings System, K903493 (secondary predicate).

807.92(a)(4) Description of the Premarket Notification Device and 807.92 (a) (5) Intended Use

The CCD is made up of two parts: Part A, which is the reusable spike assembly (intended for use on only one container of contrast media/dye and considered an extension of the contrast container) and; Part B, which is the disposable valve and tubing set (intended for use on only one patient). The two in-line backcheck valves in Part B prevent inadvertent retrograde flow thereby protecting Part A from contamination.

The clinician spikes the bottle of contrast media with Part A and then dead-ends the spike assembly until the start of the case. The clinician then attaches Part B and proceeds with the first case. When that case is complete the clinician detaches Part B and caps Part A with a new sterile dead-ender. When the clinician is ready to start the next case he attaches a new sterile Part B and proceeds. This can be repeated up to two times (for a total of three patients) within a maximum six-hour time frame.

The Contrast Control Device (CCD) is intended for use in the IV delivery of contrast media during imaging procedures with a secondary intended use of conservation of contrast media.

NDD124



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1998

Ms. Cathy Chenetski
Director, Regulatory Affairs
Medex, Incorporated
3637 Lacon Road
Hilliard, Ohio 43026

Re: K982123
Trade Name: Contrast Control Device
Regulatory Class: II
Product Code: FPA
Dated: June 11, 1997
Received: June 16, 1997

Dear Ms. Chenetski:

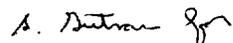
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

K982122

510(k) Number (if known) _____

Device Name: Contrast Control Device

Indications for Use:

The Contrast Control Device (CCD) is intended for use in the IV delivery of contrast media during imaging procedures with a secondary intended use of conservation of contrast media.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Patricia Cuccinelli
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

(Optional Format 1-2-96)

510(k) Number K982123

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