4/6/99

510 (k) Summary K982640

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

July 21, 1998

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

Classification Name:	Syringe Infusion Pump (80 FRN)
Common/Usual Name:	Syringe Infusion Pump
Trade/Propriety Name:	Not yet determined.
Part Number:	Medex 3000 Series

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

The Medex 3000 Series Syringe Infusion Pump, for purposes as defined under Section 510(k) of the Federal Food, Drug and Cosmetic Act, is substantially equivalent to the Medex 2000 Series Syringe Infusion Pumps K890120, K901755 and K955231 and the Baxter AutoSyringe AS50 Infusion Pump K945942 (SE decision 7/10/95). For simplicity, the Medex 2010i will be used throughout this 510(k) to represent the Medex 2000 Series Syringe Infusion Pumps as the predicate device.

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

The Syringe Infusion Pump is a software driven, microprocessor controlled, electromechanical system that contains within its case: user interface, power supply, motor, pumping mechanism, and electronic circuits required to effect the controlled infusion of fluids through a syringe and a sterile administration set. The pump operates by controlled displacement of the syringe plunger. Medex currently markets the Medex Medfusion 2000 Series Syringe Infusion Pumps under 510(k) numbers K890120, K901755 and K955231. The Medex 3000 Series Syringe Infusion Pump is the next generation syringe pump which utilizes the same method of delivery and the same basic elements.

The Medex 3000 Series Syringe Infusion Pump is intended for use in the administration of fluids requiring precisely controlled infusion rates including blood and blood products, lipids, drugs and other therapeutic fluids via arterial, epidural, intravenous, spinal and subcutaneous routes. The pumps are indicated for use in continuous, volume/time, body weight, custom dilution, intermittent or bolus delivery modes in critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the pump can be monitored or supervised by a clinician.

The Syringe Infusion Pump is not intended for use on the inlet side of extracorporeal membrane oxygenation (ECMO) systems where high negative pressures may occur.

807.92 (a) (6) Technical Characteristics Summary

Similarities between the predicate device and the 510(k) device:

- Both the Medex 3000 Series Syringe Infusion Pump and the predicate devices contain internal batteries and offer delivery databanks.

- Both the Medex 3000 Series Syringe Infusion Pump and the Baxter AS50 predicate device have a syringe flange sensor and offer a custom dilution mode.

Differences between the predicate device and the 510(k) device:

- The Medex 3000 Series Syringe Infusion Pumps offer pre-delivery (loading) bolus and post-occlusion bolus reduction features while the predicate devices do not.

- The Medex 3000 Series Syringe Infusion Pump offers a +/- 2% flow delivery accuracy rate while the predicate devices offer a +/- 3% flow delivery accuracy rate.

807.92 (b) (1), (b) (3) Performance Testing Assessment

Medex conducted flow rate testing to verify that the 3000 Series Syringe Infusion Pump meets specifications and is therefore equivalent to the predicate devices. Additionally, Medex conducted testing to confirm that the 3000 Series Syringe Infusion Pump delivered a reduction in post-occlusion bolus volume as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 1999

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

Re: K982640
Trade Name: Medex 3000 Series Syringe Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 29, 1999
Received: February 1, 1999

Dear Ms. Chenetski:

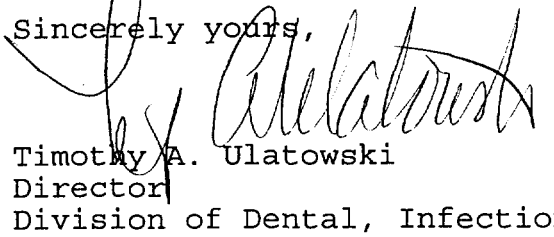
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

510(k) Number (if known) K982640

Device Name: Syringe Infusion Pump

Indications for Use:

The Medex 3000 Series Syringe Infusion Pump indications for use are as follows:

- in the administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics and other therapeutic fluids.
- in the following delivery routes: arterial, epidural, intravenous, spinal, and subcutaneous.
- in the following delivery modes: continuous, volume/time, mass, body weight, custom dilution, intermittent and bolus.
- in critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the Syringe Infusion Pump can be monitored or supervised by a clinician.
- the Syringe Infusion Pump is *contraindicated* for use on the inlet side of extracorporeal membrane oxygenation (ECMO) systems where high negative pressures may occur.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982640

(Optional Format 1-2-96)