K072603

ELIXIR CORPORATION

OCT 23 2008

510 (k) SUMMARY

This 510(k) summary regarding the substantial equivalence, safety and effectiveness of the ABC Syringe Infusion Pump Model 4100 is hereby submitted in compliance with the requirements of 21 CFR Part 807.92.

SUBMITTER INFORMATION

A.	Company Name:	Elixir Corporation
B.	Company Address:	3700 Namasco Drive, Suite C Suwanee, GA 30024
C.	Company Phone: Company Fax:	770-904-3766 770-904-3696
D.	Submitter/ Contact:	William M. Vondersmith Director, QA/RA
E.	Date Summary Prepared:	August 31, 2007

DEVICE IDENTIFICATION

A.	Device Name:	Infusion Pump
B.	Trade/Proprietary Name:	ABC Syringe Infusion Pump Model 4100
C.	Classification:	Class II
D.	Product Code:	FRN

SUBSTANTIAL EQUIVALENCE

The ABC Syringe Infusion Pump Model 4100 is substantially equivalent to the Medex (Medfusion) 3000 series (K982640 and K040899) and 2000 series (K890120, K091755, and K955231) syringe infusion pumps.

DEVICE DESCRIPTION

The ABC Syringe Infusion Pump Model 4100 is software driven and microprocessor controlled electromechanical system, powered by 120VAC converted to DC (or an internal DC battery pack if AC
power is not supplied), which is designed to allow the operator to program the infusion of fluid through a syringe and an administration set. The pump delivers fluid by controlling the displacement of the syringe plunger in accordance with the program entered by the operator.

INTENDED USE

The ABC Syringe Infusion Pump Model 4100 intended use follows:

In any area such as neonatal and pediatric intensive care, anesthesia, adult critical care or any other area where the pump use can be monitored or supervised by a trained healthcare professional where the precise administration of fluids including drugs, antibiotics, lipids, blood, blood products, enteral solutions, or other therapeutic solutions is required.

Delivery routes include: Intravenous, arterial, epidural, spinal, enteral, and subcutaneous.

Delivery modes include: Continuous, volume/time, mass, body weight, and bolus.

TECHNOLOGICAL CHARACTERISTICS

The ABC Syringe Infusion Pump Model 4100 and its predicates are software driven, microprocessor controlled electromechanical systems that meter fluids contained in a syringe though an administration set to the patient, with several selectable delivery routes and modes, as programmed by the operator on a membrane keyboard with an LCD display. The system is powered primarily by 120VAC converted to DC within the pump, or alternatively by an internal rechargeable DC battery pack if AC power is not supplied. The program's progress is displayed continuously during use to the operator on the LCD screen and LEDs to indicate its real-time status. Visual and audible alarms are given to the operator or attendant as the situation might demand, along with an end-of- program signals. These attributes are substantially equivalent to all or some of the predicate devices.

PERFORMANCE DATA

The performance data indicate that the ABC Syringe Infusion Pump Model 4100 meets the specified requirements, and therefore is substantially equivalent to the predicate devices. A comparison of the technological characteristics of the ABC Syringe Infusion Pump Model 4100 and the predicate devices was performed showing that the ABC 4100 met or exceeded the safety, effectiveness, and performance of the predicates:

1. Flow delivery and accuracy (using identified syringes).
2. Occlusion testing (using identified syringes).
3. Software validation.
4. Compliance with the following international standards (same as the predicates):

    - IEC 60601-1 Medical electrical equipment Part 1. General requirements for safety.
    - IEC 60601-1-2 Medical electrical equipment Part 1-2. General requirements for safety. Collateral standard: Electromagnetic compatibility – Requirements and tests.
    - IEC 60601-2-24 Medical electrical equipment Part 2-24. Particular requirements for the safety of infusion pumps and controllers.

Conclusion:

The results of the above performance testing and validation, and its compliance with the three comparable standards, demonstrated substantial equivalence to the predicate devices in technology, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William M. Vondersmith
Director, Quality Assurance and Regulatory Affairs
Elixir Corporation
3700 Namasco Drive, Suite C
Suwanee, Georgia 30024

Re: K072603
Trade/Device Name: ABC Syringe Infusion Pump, Model 4100
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 19, 2008
Received: September 22, 2008

Dear Mr. Vondersmith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

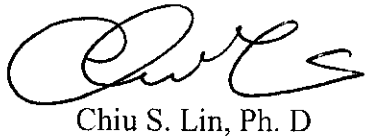
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072603

Device Name: ABC Syringe Infusion Pump Model 4100

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology. General Hospital
Infection Control. Dental Devices

510(k) Number: K072603