

Summary of Safety and Effectiveness

Introduction:

The Safe Medical Device Act (SMDA) of 1990 requires that in addition to other information submitted in a 510(k), medical device manufacturers must submit a summary of information regarding safety and effectiveness for the device subject to the 510(k). The summary is to include detailed information regarding adverse health effects of the device. This Summary of Safety and Effectiveness document is intended to comply with the SMDA requirement. FDA will make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by:

FluidSense Corporation
260 Merrimac Street
Newburyport, MA 01950

USA Contact Person:

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FluidSense Corporation
Tel: 978.499.3900 / Fax: 978.499.8634

Date Prepared:

June 10, 1998

Trade Name of Device:

FluidSense Fluid Delivery System

Common Name of Device:

Infusion Pump (FS-01)
Infusion Pump Fluid Case (FC-01)
Administration Sets (ES-01, ES-03)

510(k) Classifications:

Class II - Infusion Pump (FS-01)
Class II - Accessories, Infusion Pump (FC-01, ES-01, ES-03)

Comparison to Predicate Devices

The FluidSense Fluid Delivery System has features equivalent in safety and performance to those included on prior legally marketed infusion pumps and accessory IV sets. The FluidSense Fluid Delivery System is Substantially Equivalent to:

K870991, Model 960A Volumetric Infusion Pump, Manufactured by IMED Corporation
K912928, Lifecare 4100 PCA Infuser Plus II, Manufactured by Abbott Laboratories
K960661, Maxcess Needle Free Connector (8200), Manufactured by Solopak Medical Products

Device Description and Intended Use:

The FluidSense Fluid Delivery System is intended for continuous or intermittent administration of fluid through clinically acceptable routes such as epidural, intravenous, irrigation, or subcutaneous pathways. It is a general purpose fluid delivery system which may be used for small and large volume delivery, PCA, and delivery from bag, bottle, or syringe. The system may be used to control and monitor flow of fluids such as:

- *Drugs and electrolytes (e.g., cardiovascular drugs, antibiotics, anesthetics, analgesics, chemotherapy agents, TPN products, lipids, solutions for irrigation procedures, etc.)*
- *Whole blood and blood products*

The FluidSense Fluid Delivery System is designed for use by trained health care professionals (e.g., nurses, physicians, anesthesiologists, etc.) The FluidSense Fluid Delivery System is intended for use in the following settings:

- *Hospitals (e.g., burn / trauma units, cardiac catheter lab, critical / intensive care, delivery / post-partum, emergency room, general floor, labor / OR / anesthesia, medical / surgical, oncology, pediatrics / neonatal, post-anesthesia / recovery, etc.)*
- *Outpatient / Surgical Centers*

The intended use of the device is the same as for the predicate devices.

Technological Characteristics:

The pump uses mechanical force (piston-driven diaphragm) to propel fluids through a narrow tube. The pump uses variable pressure, inertially dominated, volumetric metering to control flow. The pump includes means to detect fault conditions, such as air in, or the blockage of, the infusion line and to activate an alarm.

The technological characteristics of the FluidSense Fluid Delivery System are the same as, or perform equivalently to, the predicate devices.

Applicable Standards and Non-Clinical Testing:

In compliance with the company's Design Controls procedures, the FluidSense Fluid Delivery System has been designed and will be tested to meet the requirements of the following standards:

- *ANSI/AAMI ID 26: Infusion Devices.*
- *UL 2601-1: Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety*
- *ISO 10993-1: Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing*
- *ISO 594-2: Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 2: Lock fittings*

Certification of the design to the above standards and the device design specifications is through a planned combination of internal design testing to written protocols and outside laboratories. No formal clinical testing has been performed, nor is any believed to be necessary.

Potential Adverse Health Effects:

The FluidSense Fluid Delivery System has been designed to either completely eliminate or mitigate known health hazards associated with the infusion of fluids. Health hazard risk reduction has been accomplished by rigorous application of a risk management program. Mitigation of health hazards identified by the risk management program were implemented by one or more of the following means (in order of preference):

1. Design modifications.
2. Detection of hazard conditions and alerting of the user through alarms and visual indications.
3. Identification of any potentially undetectable health hazard conditions in the instruction manual and other device labeling.

Several hazards resulting in clinical complications are associated with fluid infusion therapies, including infiltration, air embolism, systemic or local infection, allergic reaction, circulatory system overload, over-

infusion, under-infusion, and accidental disconnect or site injury. Other potential injuries to the patient or clinician may result from equipment damage or misuse of the device, such as electrical shock or trauma such as injury from mechanical pinch points. Every effort was taken in the design of the Fluid Delivery System to identify the nature and source of these hazards, and to identify the appropriate mitigation.

The user must be qualified in the use of the Fluid Delivery System prior to use. The user must be familiar with all labeling and instructions for use. The following information is included in the Operator's Manual and device labeling:

- *Warnings and Cautions*
- *Intended Use and Instructions for Use*
- *Fluid Delivery System Specifications*

Many device injuries are due to user error and failure to follow the instructions for use. The user of the device is advised to thoroughly understand the use of the equipment, and familiarize themselves with the location and function of all controls and alarms prior to using the equipment for the purposes of infusion therapy.

FluidSense believes that the Fluid Delivery System is safe and effective when used as instructed by knowledgeable and trained personnel, and performs as well as or better than the legally marketed predicate devices.



NOV 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Eric L. Brennan
Vice President
Clinical Services
FluidSense Corporation
260 Merrimac Street
Newburyport, Massachusetts 01950

Re: K982170
Trade Name: FluidSense Fluid Delivery System
Regulatory Class: II
Product Code: FRN
Dated: September 15, 1998
Received: September 17, 1998

Dear Mr. Brennan:

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 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). 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 requirements, 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

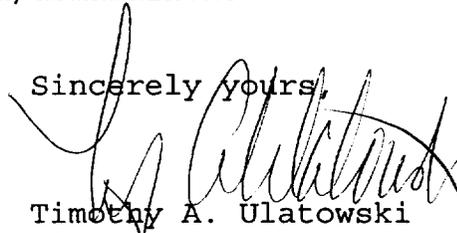
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21CFR 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/dsma/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

Indications For Use

510(k) Number (if known) K982170

Device Name: FluidSense Fluid Delivery System

Indications For Use:

The device is intended for continuous or intermittent administration of fluid through clinically acceptable routes such as epidural, intravenous, irrigation, or subcutaneous pathways. The device is intended to control and monitor the flow of fluids, which may include:

1. Drugs and Electrolytes (e.g., cardiovascular drugs, antibiotics, anesthetics, analgesics, chemotherapy agents, TPN products, lipids, solutions for irrigation procedures, etc.)
2. Whole Blood and Blood Products.

The device is intended for use in:

1. Hospitals (e.g., burn / trauma units, cardiac catheter lab, critical / intensive care, delivery / post-partum, emergency room, general floor, labor / OR / anesthesia, medical / surgical, oncology, pediatrics / neonatal, post-anesthesia / recovery, etc.)
2. Outpatient / Surgical Centers

and is intended for use by:

1. Trained health care professionals (e.g., nurses, physicians, anesthesiologists, etc.).

(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 _____

(Division Sign-Off) Brenda Baker
Division of Dental, Infection Control, (Optional Format 1-2-96)
and General Hospital Devices

510(k) Number K982170