

K053554

510(k) SUMMARY

Milestone's CompuFlo Syringe Pump

JUL 10 2006

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Howard Holstein
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Phone: (202) 637-5600

Date Prepared: December 20, 2005

Name of Device and Name/Address of Sponsor

CompuFlo™ Infusion Pump

Milestone Scientific, Inc.
220 S. Orange Avenue
Livingston, NJ 07039

Common or Usual Name

Syringe Infusion Pump

Classification Name

Infusion Pump, Class II, 21 C.F.R. § 880.5725

Predicate Devices

- Harvard Clinical Technology, Inc.'s Harvard 2 Syringe Pump (K050107)
- Alaris Medical Systems, Inc.'s Medley Syringe Pump Module (K023264)
- Medex, Inc.'s Medex 3000 Series Infusion Pump (K040899)

K053554

Intended Use / Indications for Use

The CompuFlo is intended for use in delivering medication and other fluids in a controlled manner. The CompuFlo is indicated for use in adults for the continuous or intermittent delivery of medications and other fluids through intravenous, intra-arterial, subcutaneous, epidural and enteral routes.

Technological Characteristics

The CompuFlo unit consists of a motor-driven piston syringe pump with an internal pressure transducer, an external pressure transducer (Meritrans™ Disposable Pressure Transducer (K920977)), a syringe retainer, a computer processor, a liquid crystal display (LCD), and a power supply. All but the external pressure transducer are contained in a plastic cabinet. A foot pedal and power cord are also included. The unit operates with a variety of user-provided disposable supplies, including Luer Lock plastic piston syringes, plastic syringe tubing, and needles.

Performance Data

Machine performance of the CompuFlo was evaluated, in addition to the software items. The evaluation of machine performance included: travel distance of the syringe plunger and the volume dispensed; the volumes dispensed; the flow rates; the force measurements on the syringe platform; and, assessing the accuracy of the internal and external pressure sensors. Pressure testing was conducted in a static fashion. With the exception of several minor tests not directly related to device performance and explained in detail in **Section XVI**, the CompuFlo functioned as intended. These test results demonstrate that the CompuFlo can accurately dispense a desired quantity of medication or fluid, and is capable of calculating the pressure at the needle tip according to the equation described in this 510(k) notice.

Substantial Equivalence

The CompuFlo raises no new questions of safety or effectiveness as compared to Harvard Clinical Technology, Inc.'s Harvard 2 Syringe Pump (K050107), Alaris Medical Systems, Inc.'s Medley Syringe Pump Module (K023264), and Medex, Inc.'s Medex 3000 Series Infusion Pump (K040899). The CompuFlo has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the CompuFlo and its predicate devices raise no new issues of safety or effectiveness. Thus, the CompuFlo is substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Milestone Scientific, Incorporated
C/O Mr. Howard Holstein
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K053554
Trade/Device Name: CompuFlo
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 27, 2006
Received: June 27, 2006

Dear Mr. Holstein:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

A handwritten signature in black ink that reads "Chiu Lin, Ph.D." with a stylized flourish at the end.

Chiu Lin, Ph.D.

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 Statement

510(k) Number (if known): K053554

Device Name: CompuFlo

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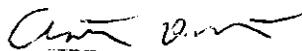
Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Signature)
Department of Anesthesiology, General Hospital,
Device Control, Dental Devices

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