



Food and Drug Administration  
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June 9, 2017

Milestone Scientific, Inc.  
Stephen Solomon  
Director, Engineering and Regulatory Affairs  
220 South Orange Ave.  
Livingston, New Jersey 07039

Re: K161883

Trade/Device Name: CompuFlo Epidural Computer Controlled Anesthesia System  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: FMF  
Dated: April 28, 2017  
Received: May 1, 2017

Dear Stephen Solomon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Lori A. Wiggins -S6**

Lori A. Wiggins, MPT, CLT  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K161883

Device Name  
CompuFlo Epidural Computer Controlled Anesthesia System

Indications for Use (Describe)

The CompuFlo Epidural Computer Controlled Anesthesia System is intended for use with an epidural needle for the real time verification of needle tip placement in the lumbar epidural space in patients over the age of 18 who are required to have epidural needle placement as part of a medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider. Once Health Care Provider verifies the epidural needle placement in the lumbar epidural space, CompuFlo Epidural Computer Controlled Anesthesia System is disconnected and HCP continues with the medical procedure.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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510(k) SUMMARY

**Milestone Scientifics' CompuFlo Epidural Computer Controlled Anesthesia System**

**Submitter**

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Date Prepared: June 6, 2017

**Trade Name of Device**

CompuFlo Epidural Computer Controlled Anesthesia System

**Sponsor:**

Milestone Scientific, Inc.  
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Livingston, New Jersey 07039

**Contact Name:**

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**Common or Usual Name:** Piston Syringe (21 CFR 880.5860, Product code: FMF)

**Predicate Devices**

- Primary predicate device: Exmoor Plastics Limited, Epidrum (K093863)
- Reference device: Milestone Scientific, Inc. CompuFlo Infusion Pump (K053554)

**Intended Use / Indications for Use**

The CompuFlo® Epidural Computer Controlled Anesthesia System is intended for use with an epidural needle for the real-time verification of needle tip placement in the lumbar epidural space in patients over age of 18 who are required to have epidural needle placement as part of a medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider.

Once Health Care Provider verifies the epidural needle placement in the lumbar epidural space, CompuFlo® Epidural Computer Controlled Anesthesia System is disconnected and the HCP continues with the medical procedure.

### Device Description

The device consists of: (1) the primary unit, (2) a pneumatic foot pedal control, (3) an AC power cord and (4) single-use disposable kit, which include an external in-line fluid pressure sensor, a 20 mL plastic syringe, plastic tubing and an ID Adapter. Operation of the device is allowed when powered by the AC mains or by the internal battery source. The epidural needle and solution is not supplied in the disposable Kit.

### Technological Characteristics

The CompuFlo® Epidural Computer Controlled Anesthesia System includes an injection-molded plastic housing that contains the motor-driven piston syringe pumps and internal force sensor, syringe retainer, microprocessor, and LCD screen display. A foot pedal and power cord are also included; the user controls the epidural needle placement verification by use of the LCD user interface and optionally the foot pedal. The tray of single-use disposable supplies includes an external in-line fluid pressure sensor, a 20 mL plastic syringe, tubing set and an adapter that limits use of the disposables to a single use. Both the CompuFlo Epidural and the reference device, the CompuFlo Infusion Pump use the same technology to control the infusion according to the operator's preferences.

### Performance Data

Testing of the CompuFlo Epidural device was carried out to meet elements of FDA's Draft Guidance *Total Product Life Cycle: Infusion Pump-Premarket Notification [510(k)]*. Performance of the device and controlling software was evaluated via non-clinical testing, addressing such subjects as syringe plunger travel distance, volume dispensed, flow rates, and the accuracy of displays monitoring pressure at the needle tip. The results of these tests demonstrate that the device is as safe and as effective, and performs as well as, if not better than, the predicate device. Testing was conducted at various flow rates and head pressures to ensure that the instrument not only functions at nominal conditions but also at the extreme limits of the instrument's specifications. Bench data demonstrated that the CompuFlo Epidural has substantially equivalent performance as the predicate device.

A summary of the non-clinical testing is provided in table below.

**Table 1: Summary of Non-clinical Testing**

Non-Clinical	Standard / Bench Testing
Electrical Safety	IEC 60601-1:2012, 3rd edition, Medical Electrical Equipment – Part 1 General Requirements for Safety and found to meet all applicable causes.
EMC	IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1; General Requirements for Safety – Section 2: Collateral Standard- Electromagnetic Compatibility – Requirements and Tests and found to meet all applicable causes.

Non-Clinical	Standard / Bench Testing
Infusion Pump	IEC 60601-2-24:2012, Medical Electrical Equipment, Particular Requirements for the Safety of Infusion Pumps and found to meet all applicable causes.
Alarms	IEC 60601-1-8:2012, Medical Electrical Equipment, Parts 1-8: General Requirements for Safety-Collateral Standard – General Requirements, tests and Guidance for Alarm Systems and found to meet all applicable causes.
Mechanical Testing	Vibration and shock testing per MIL-STD 810G Method 514.6 Procedure 1 and Method 516.6 Procedure 1 and found to meet all applicable causes.
Environmental Testing	Altitude, Temperature and Humidity per Mil-STD 810G Method 500.5 Procedure 1; Method 501.5 Procedure 1 and 2; Method 502.5 Procedure 2; and found to meet all applicable causes.
Drop Test	Testing to confirm that the instrument can function and or not create a hazard under an adverse condition of a 6 inch and 12 inch drop on a hard surface.
Software	Developed and maintained per IEC 62304 and conducted according to FDA guidance titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)"
System Integration Test	Conformance Verification.
Sterilization	External In-Line Fluid Pressure Sensor, tubing set and syringe are sterilized using a validated 100% ethylene oxide (EO) sterilization process to SAL of six log reduction according to ANNSI/AAMI/ISO 11135-1:2007 as previously cleared by FDA
Cybersecurity	Cybersecurity risk assessment and management was conducted according to FDA guidance titled, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)".
Biocompatibility	The CompuFlo Epidural instrument does not come in direct contact with the patient. Components that have indirect contact with the patient were previously cleared by the FDA. Additional testing was conducted per ISO 10993-18 as part of an overall risk analysis and found to meet applicable clauses.
Human Factors	Milestone conducted a human factors/usability study according to FDA guidance document titled, "Applying Human Factors and Usability Engineering to Optimize Medical Device Design (June 22, 2011)". Study results demonstrated that participants were able to adequately use the device.
Dose Accuracy	Dose accuracy testing was conducted comparing the dose accuracy of CompuFlo Epidural to the referenced CompuFlo (K053554) instrument. Six test points were used to confirm the dose accuracy. The average variation between the reported and actual fluid dispensed was 0.316% for the CompuFlo Epidural and 3.2% for the CompuFlo (K053554).
Zero Pressure	The Zero Pressure test was conducted to demonstrate the system's ability to compensate for vertical displacement by using the Zero Pressure button.

## Clinical Study

CompuFlo Epidural was evaluated in a prospective, randomized, controlled, parallel group, multicenter, pivotal study. The purpose of this pivotal study was to demonstrate the performance of the CompuFlo® Epidural Computer Controlled System for the epidural

space verification when compared to the loss of resistance technique (LOR). The primary objective of the COMPASS study was to determine whether the success rate of performance of lumbar epidural anesthesia with the CompuFlo Epidural to identify the epidural space is equivalent to performance of lumbar epidural anesthesia with the LOR technique. A total of 400 subjects were enrolled at 6 US clinical centers, of which two-hundred-forty subjects (240) required epidural procedure as part of the chronic pain management and one-hundred-sixty (160) required epidural procedure for acute pain management during labor and delivery. Twelve (12) subjects (3% of the total population enrolled) did not have epidural procedure performed, so total of 388 procedures were performed as part of the study. The study data demonstrated the performance of the CompuFlo Epidural for the epidural space verification. The primary outcome hypothesis that the Experimental Procedure Group (EPG) is non-inferior to the Standard Care Group (SCG) with respect to the primary endpoint of successful performance of lumbar epidural procedure, where the non-inferiority margin (delta) is an absolute difference of 1 percent has been met.

Based on the nonclinical and clinical tests conducted, it was demonstrated that the CompuFlo Epidural device is as safe, as effective and performs as well as or better than the legally marketed device identified above.

### Substantial Equivalence

The CompuFlo Epidural Computer Controlled Anesthesia System is substantially equivalent to the Exmoor Plastics Limited's Epidrum cleared under K093863.

**Table 2: Comparison between Milestone CompuFlo Epidural and Predicate device**

Feature	Subject Device: Milestone CompuFlo Epidural	Primary Predicate Device: Exmoor Plastics Limited Epidrum (K093863)	Reference Device: Milestone CompuFlo Infusion Pump (K053554)
<b>Indication for Use</b>	<p>The CompuFlo® Epidural Computer Controlled Anesthesia System is intended for use with an epidural needle for the real-time verification of needle tip placement in the lumbar epidural space in patients over age of 18 who are required to have epidural needle placement as part of the medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider.</p> <p>Once Health Care Provider Computer Controlled Anesthesia System verifies the epidural needle placement in the lumbar epidural space, CompuFlo® Epidural is disconnected and the HCP continues with the medical procedure.</p>	<p>The Epidrum is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space.</p>	<p>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.</p>

Feature	Subject Device: Milestone CompuFlo Epidural	Primary Predicate Device: Exmoor Plastics Limited Epidrum (K093863)	Reference Device: Milestone CompuFlo Infusion Pump (K053554)
<b>User Population</b>	18 years of age and older	Adults	Adults
<b>Principal of Operation / Technological Differences</b>	The CompuFlo Epidural uses an in-line fluid pressure sensor to accurately measure the pressure at the needle which provide visual and audio indication that the needle has entered the epidural space	The Epidrum comprises a small chamber, featuring a female Luer inlet port and a male Luer exit port on opposing sides, with an expandable membrane as one of the sides between the pods	CompuFlo Infusion uses an in-line fluid pressure technology to deliver fluids with pressure monitoring and integral alarms
<b>Disposables</b>	<ul style="list-style-type: none"> <li>• Commercial syringe, 20 ml sizes, provided by Milestone</li> <li>• Commercially available needles provided by clinician</li> <li>• Tubing Set provided by Milestone</li> <li>• ID Adaptor provided by Milestone</li> </ul>	<ul style="list-style-type: none"> <li>• User-provided, commercially available disposable supplies, such as off-the-shelf vials and off-the-shelf needles</li> <li>• Disposable hand piece and tubing</li> </ul>	<ul style="list-style-type: none"> <li>• Commercially available syringes of various sizes provided by clinician</li> <li>• Commercially available needles provided by clinician</li> <li>• Commercially available hand piece provided by Milestone</li> </ul>

Milestone's CompuFlo Epidural Computer Controlled Anesthesia System and the primary predicate Epidrum have the same intended use of verifying the placement of the epidural needle in the epidural space. The CompuFlo Epidural Controlled Anesthesia System additionally achieves the primary intended use in real-time whereas Epidrum, the predicate device does not. In addition, CompuFlo Epidural Controlled Anesthesia System is specifically indicated for patients over the age of 18 years old, which was established based on the COMPASS Clinical study, whereas the Epidrum was indicated for use in adults. The aforementioned difference is not critical to the intended therapeutic or diagnostic use of the device and the differences do not affect the safety and effectiveness of the device when used as labeled.

Both devices also have similar technological characteristics of using pressure sensing based on the well-known and widely used loss of resistance technique; difference between CompuFlo Epidural Controlled Anesthesia System and Epidrum is technology that is used to provide visual and audio indication that the needle has entered the epidural space. CompuFlo Epidural Controlled Anesthesia System uses computer controlled objective measurement of the pressure changes at the tip of the needle, whereas Epidrum relies on the subjective audio and visual indication of the pressure changes. As stated above, differences are not critical to the intended therapeutic or diagnostic use of the device, and the differences do not raise different questions of safety and effectiveness of the device when used as labeled. Furthermore once Health Care Provider (HCP) verifies the epidural needle placement in the lumbar epidural space, the CompuFlo® Epidural is disconnected and the HCP continues with the medical procedure. The Epidrum indications for use does not

address this step, however from the labeling/instructions for use that step is also completed with the Epidrum, thus there is no difference.

The CompuFlo Epidural uses an in-line fluid pressure sensor to accurately measure the pressure at the needle, which provides visual and audio indication that the needle has entered the epidural space. In comparison, the Epidrum uses a small pressure chamber that provides a visual indication that the needle has entered the epidural space. Although the method of pressure sensing is different, both provide feedback to the user regarding the loss of pressure as the needle enters the epidural space. The pressure sensor in the CompuFlo Epidural provides an objective and accurate pressure measurement to the user. In addition, FDA has cleared similar pressure sensing technology in the company's reference CompuFlo device (K053554). As such, any differences in technological characteristics do not raise different questions of safety or effectiveness. Furthermore, bench testing and clinical study data have demonstrate substantially equivalent performance. Accordingly, the CompuFlo Epidural is substantially equivalent to the primary predicate Epidrum.