February 25, 2023

Milestone Scientific, Inc.
% Kevin Go
Consultant
Rqm+
2790 Mosside Blvd.
Monroeville, Pennsylvania 15146

Re: K221702
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: January 25, 2023
Received: January 26, 2023

Dear Kevin Go:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221702

Device Name
CompuFlo® Epidural Computer Controlled Anesthesia System

Indications for Use *(Describe)*
The CompuFlo® Epidural Computer Control Anesthesia System is intended for use with an epidural needle for the real-time verification of needle placement in the lumbar or thoracic epidural space, inclusive of cervicothoracic junction (CTJ). It is intended for patients over age of 18 who are required to have epidural needle or catheter placement as part of a medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider (HCP).

The CathCheck is an additional feature for clinicians to use to assess proper catheter placement inside the epidural space by evaluating a pulsatile waveform. The CathCheck function utilizes the same technology as the CompuFlo® Epidural Computer Control Anesthesia System and should only be used in conjunction with standard clinical assessment practice.

Once the Health Care Provider verifies the epidural needle or catheter placement in the epidural space, the 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.

510(k) Summary

DATE PREPARED
February 19, 2023

MANUFACTURER AND 510(k) OWNER
Milestone Scientific, Inc.
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Kevin Go, MBA, RAC, CQA
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DEVICE INFORMATION
Proprietary Name/Trade Name: CompuFlo® Epidural Computer Controlled Anesthesia System
Regulation Number: 21 CFR 880.5860
Class: Class II
Product Code: FMF
Review Panel: General Hospital

PREDICATE DEVICE IDENTIFICATION
The CompuFlo® Epidural Computer Controlled Anesthesia System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate/Reference*
K161883	CompuFlo® Epidural Computer Controlled Anesthesia System	Predicate
K201356	Plastic LOR Syringe	Reference

The predicate devices have not been subject to a design related recall.

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 can 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

INDICATIONS FOR USE

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The CathCheck is an additional feature for clinicians to use to assess proper catheter placement inside the epidural space by evaluating a pulsatile waveform. The CathCheck function utilizes the same technology as the CompuFlo® Epidural Computer Control Anesthesia System and should only be used in conjunction with standard clinical assessment practice.

Once the Health Care Provider verifies the epidural needle or catheter placement in the epidural space, the HCP continues with the medical procedure.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

This submission introduces several changes to the previously cleared submission including expanding the indications for use to include use in the thoracic space, compatibility with a catheter component (CathCheck program), modification to the packaging configuration for the disposable kits, and minor changes to the software. Milestone Scientific, Inc. believes that the CompuFlo® Epidural Computer Control Anesthesia System is substantially equivalent to the predicate devices based on the information summarized here:

The proposed CompuFlo® Epidural Computer Controlled Anesthesia System has the same intended use, environment of use, materials, operating principle, and fundamental technology as the predicate device. A clinical study has been conducted to demonstrate the safety and effectiveness of the device in the newly proposed thoracic indication. Software verification and validation have been completed to ensure the functionality of the new software features and address any residual risks. Finally, sterilization and packaging validation has been conducted to establish the acceptability of the new packaging configuration for the disposable kits. Therefore, the information provided in this submission supports safety and effectiveness of the proposed device for its intended use and demonstrates substantial equivalence to the predicate device.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

Performance Category	Testing
Sterilization Validation	Sterilization validation has been completed on the worst-case construct to an SAL of $1x10^{-6}$.

Packaging Validation	Packaging performance validation, in accordance with ISO 11607-1:2019 and ISO 11607-2:2019, was performed on the final packaging and sterilized device.
Software Verification and Validation	Software verification and validation in accordance with the appropriate Level of Concern as described in FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005

The results of these tests indicate that the CompuFlo® Epidural Computer Controlled Anesthesia System is substantially equivalent to the predicate devices.

SUMMARY OF CLINICAL TESTING

The purpose of this investigation study is to demonstrate that the safety and efficacy profile of the CompuFlo Epidural System for thoracic epidural placement is substantially equivalent to the traditional LOR technique. This study was a prospective, controlled, mono-center, parallel-group randomized trial in the US. A total of 133 subjects were enrolled at a single site. The study evaluated patients aged 18 – 75 years old with BMIs ranging from 18 -50 kg/m^2.

The primary endpoint of the study was successful performance of thoracic epidural placement. The CompuFlo group has a 96.7% success rate compared to a 91.2% success rate of the traditional LOR technique. The results of the primary efficacy endpoint demonstrated a success rate that was not statistically superior to the control. No significant difference on primary success rate was detected between the two study groups.

Regarding the safety endpoint, two (2) accidental dural punctures were observed in both groups. No other adverse events except for hypotension were reported during the study in the CompuFlo group. The overall observed hypotension was mild and patients were treated per routine protocol. Furthermore, the principal investigator judged the causal relationship as “not related” to the CT treatment since this adverse event was observed in both treatment groups.

CONCLUSION

Based on the evaluations performed, including sterilization validation, packaging validation, software verification and validation and Milestone’s clinical study, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate or reference devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed CompuFlo® Epidural Computer Controlled Anesthesia System are assessed to be substantially equivalent to the predicate and reference devices.