March 18, 2020

Maquet Critical Care AB
% Mark Smith
Sr. Regulatory Affairs Specialist
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K191027
Trade/Device Name: Flow-i Anesthesia System, Flow-c Anesthesia System, Flow-e Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: February 17, 2020
Received: February 18, 2020

Dear Mark Smith:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191027

Device Name
Flow-i Anesthesia System
Flow-c Anesthesia System
Flow-e Anesthesia System

Indications for Use *(Describe)*
The indication for Flow-i/Flow-c/Flow-e Anesthesia System is administering inhalation Anesthesia while controlling the entire ventilation of patients with no ability to breathe, as well as in supporting patients with a limited ability to breathe. The system is intended for use on neonatal to adult patient populations. The system is intended for use in hospital environments, except MRI environment, by healthcare professionals trained in inhalation Anesthesia administration.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

as required by section 21 CFR 807.92

Device owner	Maquet Critical Care AB Röntgenvägen 2 SE-171 54 Solna, Sweden Tel: (011) 46 10 335 7300
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Application Correspondent:	Mr. Mark N. Smith Manager, Regulatory Affairs Getinge 45 Barbour Pond Drive Wayne, NJ 07470 Email: mark.n.smith@getinge.com Phone: 585-272-5274

Date prepared: March 18, 2020

Trade Name:	**Model:**
Flow-i Anesthesia System	Flow-i C20 Flow-i C30 Flow-i C40
Flow-c Anesthesia System	Flow-c
Flow-e Anesthesia System	Flow-e

Device Classification

Common Name	Gas-Machine, Anesthesia
Classification Number	BSZ
Class	II
Regulation Number	21 CFR 868.5160

Predicate Device Identification

Maquet FLOW-i Anesthesia System	K160665

Reference Device Identification

GE Aisys CS2	K170872

Indications for Use

The indication for the Flow-i/Flow-c/Flow-e Anesthesia system is administering inhalation Anesthesia while controlling the entire ventilation of patients with no ability to breathe, as well as in supporting patients with a limited ability to breathe. The system is intended for use on neonatal to adult patient populations. The system is intended for use in hospital environments, except MRI environment, by healthcare professionals trained in inhalation Anesthesia administration.

Intended use of the Device

The system is intended for use in administering Anesthesia while controlling the entire ventilation of patients with no ability to breathe, as well as in supporting patients with a limited ability to breathe.

The system is intended for use by healthcare professionals, trained in the administration of Anesthesia.

The system is intended for use on neonatal to adult patient populations.

The system is intended for use in hospital environments, except MRI environment. When not in operation, the system is designed for in-hospital transport.

Device Description

Flow-i, Flow-c and Flow-e Anesthesia systems within the Flow Anesthesia family 4.7 are high-performance Anesthesia systems designed to meet the many ventilatory challenges within Anesthesia, as well as to provide inhalation Anesthesia. It is intended to serve a wide range of patients from neonatal to adult.

Flow Anesthesia family is a software-controlled semi-closed system for inhalation Anesthesia (Sevoflurane, Desflurane, Isoflurane and/or nitrous oxide).

The Flow-i/-c/-e 4.7 consists of a core, where gases are mixed and administered, and a User Interface where the settings are made and ventilation and anesthesia are monitored.

The Flow-i/-c/-e 4.7 is based on the cleared predicate device FLOW-i 4.2 (K160665) with some improvements.

COMPARISON TO PREDICATE

Comparison of Intended Use
The Intended Use for the modified Flow-i, Flow-c and Flow-e Anesthesia systems within the Flow Anesthesia family version 4.7 is identical to the predicate device, FLOW-i Anesthesia System version 4.2 (K160665).

Comparison of Technology Characteristics
The following changes have been made to Flow-i/-c/e 4.7 compared to the cleared predicate device FLOW-i 4.2 (K160665) without significant change with regards to safety and/or effectiveness:

- A new function that supports lung recruitment of patients

  The subject devices Flow-i, Flow-c and Flow-e Anesthesia systems within the Flow Anesthesia family version 4.7 introduces a function that facilitates the lung recruitment maneuver (RM) by displaying a breath-by-breath presentation of relevant breathing parameters, i.e. End Inspiratory Pressure (EIP), Positive End Expiratory Pressure (PEEP) and Dynamic Compliance (Cdyn). It is available as Automatic RM and as RM trends (manual recruitment).

  The added function RM is substantially equivalent to the recruitment maneuver in the reference device (K170872) and does not affect the overall performance or technology of the device.

- Modifications of the Patient Gas Analyzer (PGA)

The subject devices' PGA component has been updated from the AION™ to the AION™ Platinum version. The AION™ PGA had the patient O2 sensor as a stand-alone component within the AION™ PGA, whereas the updated AION™ Platinum includes the O2 sensor and the gas analyser within the same component housing.

The exchange of the Patient Gas Analyzer AION™ to the AION™ Platinum does not affect the overall performance or technology of the device, as it does not affect the anesthesia delivery, the monitoring of ventilation or the alarm handling.

- A new user interface indicator, MAC Brain

  The display of the MAC value has been updated to include a bar indicator on the user interface. This bar indicator now includes MAC Brain and is shown side by side with the MAC value. The purpose of MAC Brain is to display the delay of the variation of agent level in the brain compared to the observed exhaled agent level. The MAC Brain value is based on the MAC value and is trended.

  The addition of MAC Brain does not affect the overall performance or technology of the device, as it does not affect the anesthesia delivery, the monitoring of ventilation or the alarm handling.

- Addition of a Pause function

  A new pause function is introduced in the subject devices for the possibility to temporarily disconnect the breathing circuits in clinical situations (e.g. for removing condensed water or repositioning the patient). The pause function can be used both in both automatic and manual ventilation.

  The Pause function is present in the cleared predicate device FLOW-i 4.2 through a manual action. In the subject device the Pause function is now supported by automatic timings.

- Option to set lower fresh gas flow

  The lower level for the fresh gas flow into the breathing system will be possible to adjust from 0.1 l/min, as compared to 0.3 l/min in the predicate device FLOW-i 4.2.

  Oxygen supply is maintained through the rebreathing system via the volume reflector in the same way as in the cleared predicate device FLOW-i 4.2. This change does not affect the overall performance or technology of the device.

- Hardware changes to the subject devices to improve supply and production
  - A new battery.
  - Modified inspiratory channel and pneumatic block.
  - Removal of the secondary, electronically controlled, locking of the vaporizer latch.
  - Introduction of a new Power Supply Unit (PSU) with the same specifications as used in the predicate device FLOW-i 4.2.

These hardware changes do not affect the overall performance or technology, as they do not change the anesthesia delivery, the monitoring of ventilation or the alarm handling.

- Minor changes to equipment labels.
  - Adding equipment enclosure IP21 rating.

The change of IP classification improves the rating of the electrical protection for the cabinet, but does not affect the anesthesia delivery, the monitoring of ventilation or the alarm handling in the sense that it affects the substantial equivalence.

- Minor Software updates.
  - Adaption of the software to the changes stated above, i.e. patient gas analyzer modifications, battery handling and modifications of the inspiratory channel and pneumatic block.
  - Adaption in the software to support SW options for Flow-c and Flow-e. These SW options are included in the standard settings for Flow-i.
  - Updated range for Air, O2, N2O supply pressure
  - Updated accuracy of CO_2 gas measurement range 0-1%.
  - Quick settings in the user interface for O_2 concentration, Fresh gas flow (FGF) and agent concentration.
  - System Check Out (SCO) improvements.

These minor software changes do not affect the overall performance or technology, as they do not change the anesthesia delivery, the monitoring of ventilation or the alarm handling.

- Addition of two new device models Flow-c Anesthesia System and Flow-e Anesthesia System.

  The addition of two new models does not affect the overall performance or technology, as they do not change the anesthesia delivery, the monitoring of ventilation or the alarm handling.

- Material changes in:
  - The filter in the patient gas pathway
  - Volume reflector
  - Vaporizers
  - Inspiratory and pneumatic block
  - The water trap membrane (used in the Patient Gas Analyzer)

  These material changes do not affect the overall performance or technology, nor were they found to raise different questions about safety and effectiveness compared to the cleared predicate device.

Similarities and differences

The subject devices are similar in all aspects, except from what is stated above, to the cleared predicate device. The modifications above do not individually, or as a sum, impact device safety and effectiveness or change the technology or performance compared to the cleared predicate device (K160665).

Non-clinical Testing and Performance

Maquet Critical Care has conducted risk analysis and performed necessary verification and validation activities to demonstrate that the design output of the modified devices meets the design input requirements:

Software

- Code review
- Static code analysis
- System testing

Performance

- System testing

- Regression
- Free User testing
- Waveform testing
- Comparative testing for MAC Brain
- Comparative testing for Recruitment Maneuver

Biocompatibility

- Volatile Organic Compounds
- Particulate Testing

Human Factors Validation Testing

The following product standards are included in the verification:

- ANSI/AAMI ES 60601-1:2005 + A1:2012, Medical electrical equipment Part 1: General requirements for basic safety and essential performance, Recognition Number 19-4
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and Test, Recognition Number 19-8
- IEC 60601-1-8:2006 + A1:2012, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, Recognition Number 5-76
- ISO 80601-2-13:2011, Medical electrical equipment -- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation, Recognition Number 1-104
- ISO 80601-2-55:2011, Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors, Recognition Number 1-96

The connector to high-pressure gas is verified according to CGA V-5:2008, Recognition Number 1-81.

Conclusion for Substantial Equivalence

The Flow-i/-c/-e Anesthesia Systems version 4.7 have identical intended use and indications for use as the predicate FLOW-i version 4.2 (K160665). Maquet has conducted risk analysis and performed necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements. The proposed changes do not affect the safety and effectiveness compared

to the predicate device FLOW-i Anesthesia System. Maquet Critical Care AB has concluded that the Flow-i, Flow-c and Flow-e Anesthesia systems within the Flow Anesthesia family version 4.7 (K191027) is substantially equivalent to the cleared predicate device, FLOW-i Anesthesia System version 4.2 (K160665).