DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 29, 2017

Maquet Critical Care AB
c/o Mark Dinger
Senior Regulatory Affairs Specialist
Maquet Medical Systems USA
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Wayne, New Jersey 07470

Re: K160665
Trade/Device Name: Flow-i Anesthesia System C20, Flow-i Anesthesia System C30, Flow-i Anesthesia System C40
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: February 28, 2017
Received: March 1, 2017

Dear Mark Dinger:

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 yours,

Tina Kiang
-S

Tina Kiang, Ph.D.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160665

Device Name
FLOW-i Anesthesia System C20, FLOW-i Anesthesia System C30, FLOW-i Anesthesia System C40

Indications for Use *(Describe)*
The indication for FLOW-i 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.

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510(k) SUMMARY
as required by section 21 CFR 807.92

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Date prepared: March 2, 2016

Trade Name:
FLOW-i Anesthesia System C20
FLOW-i Anesthesia System C30
FLOW-i Anesthesia System C40

Device Classification

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

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Maquet FLOW-i Anesthesia System version 3.0	K133958

Indications for Use

The indication for FLOW-i 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 Anesthesia System is a Anesthesia system 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-i Anesthesia System is a software-controlled semi-closed system for inhalation Anesthesia (Sevoflurane, Desflurane, Isoflurane and/or nitrous oxide).
The most important performance features of the FLOW-i Anesthesia System are:

- a ventilator whose functionality is based on ICU-ventilator technology,
- the volume reflector technology,
- the electronically controlled injector vaporizers and
- the ergonomic design.

This 510(k) submission for the FLOW-i Anesthesia System is based on the following modifications:

- Updates of the product for compliance with 3rd edition of the 60601 standard package
    - IEC 60601-1:2005
    - ISO 80601-2-13:2011
    - ISO 80601-2-55:2011
- Implementation of a new function that provides recommended ventilation values (PBW)
- Possibility to set a lower alarm limit for the Airway pressure alarm: High
- Display of Airway resistance measurement following an Inspiratory and/or Expiratory Hold

Non-clinical Testing and Performance

The following characteristics of FLOW-i Anesthesia System were tested: technical data, measurement ranges and measurement accuracy, delivery accuracy, construction, features, interfaces, handling, critical situations and interventions.

The design verification activities for the modified FLOW-i Anesthesia System version 4.2 consist of:

- Requirement verification of affected requirements
- Regression testing
- Free User Testing
- Code review and static code analysis
- Verification of applicable product standards
    - AAMI/ANSI ES 60601-1:2005 and A1:2012, Recognition Number 19-4
    - IEC 60601-1-2:2007, Recognition Number 19-1
    - AAMI/ANSI/IEC 60601-1-8:2006, Recognition Number 5-92
    - ISO 80601-2-13:2011, Recognition Number 1-104
    - ISO 80601-2-55:2011, Recognition Number 1-96
    - ISO 5356-1:2004, Recognition Number 1-62
    - ISO 5360:2012, Recognition Number 1-91
    - CGA V-5:2008, Recognition Number 1-81

Design validation has been performed in order to ensure the product meets its intended use and user needs.

Design verification and validation has demonstrated that the FLOW-i Anesthesia System performs within its specifications and within the limits of the applied performance standards.

Clinical Investigation

The functionality added in the proposed FLOW-i Anesthesia System version 4.2 does not add any new functions that need to be validated by clinical investigation.

CHANGES AND SUBSTANTIAL EQUIVALENCE DISCUSSION

Comparison of Intended Use
The Intended Use for the modified FLOW-i Anesthesia System version 4.2 is identical to the predicate device, FLOW-i Anesthesia System version 3.0 (K133958).

Comparison of Technology Used
There are minor changes in the technological characteristics for the modified FLOW-i Anesthesia System version 4.2 compared to the predicate device FLOW-i Anesthesia System version 3.0 (K133958). See below.

Similarities and differences
The main improvements introduced in the modified FLOW-i Anesthesia System version 4.2 from the predicate device FLOW-i Anesthesia System version 3.0 (K133958) are:

Updates of the product for compliance with 3rd edition of the 60601 standard package

The second edition Anesthesia standard, IEC 60601-2-13:2003, gave the manufacturer the option to choose between BTPS (Body Temperature and Pressure ambient, Saturated humidity) and ambient. The third edition Anesthesia standard, ISO 80601-2-13:2011, mandates BTPS.
The predicate version of FLOW-i presented volumes as AP21 (Ambient Pressure at 21%, dry).
The subject FLOW-i Anesthesia System version 4.2 presents volumes as appearing at the Y-piece by the patient interface as BTPS – volumes presented are compensated for normal body temperature (37°C), ambient pressure and relative humidity (100%).

A new function that provides recommended ventilation values (PBW)

A new function that provides reasonable good ventilation setting start values which are confirmed by the user. Based on entered patient category, gender, weight, and length start-up values for the Respiratory Rate (RR), the Tidal Volume (TV) or the Minute Volume (MV) are suggested.
In mechanical ventilation this function can be used to help reduce the risk that differences in body weight will affect the estimated ventilation needs for different patients. Once the user has started ventilating the patient, the user will fine tune the settings.

Possibility to lower the alarm limit for the Airway pressure alarm: High

The lower alarm limit for the Airway pressure alarm: High will be possible to set to 10 cmH_2O, previously 16 cmH_2O.

Display of Airway resistance measurement

Following an Inspiratory and/or Expiratory Hold, FLOW-i will in addition provide measurement of the airway resistance.

Other minor modifications to the FLOW-i Anesthesia System 4.2 consist of:

Software upgrades:

- Vaporizer improvements
- System Check Out (SCO) improvements
- Improvement of O_2 measurement
- Improvements to the FLOW-i Communication Interface (FCI)

None of the modifications above implemented in the modified FLOW-i Anesthesia System version 4.2 raise any new type of questions of safety and effectiveness.

Labeling changes:
Updates of labelling for compliance with 3rd edition of the 60601 standards package

None of the labeling changes implemented in the modified FLOW-i Anesthesia System version 4.2 changes the technology or performance of the FLOW-i Anesthesia System.

Hardware/Accessories changes:

- US power outlets have been added as an option for the power outlets. In the previous FLOW-i version only IEC power outlets existed. The only change is the power outlets. No other change has been made to the isolation transformer.

- The CO_2 absorber switch will be changed to a two position switch.

- The two hand grip to open the patient cassette lid has been replaced with a one hand grip. The window on the top of the lid will be enlarged for visibility of the inspiratory and expiratory valves.

None of the hardware/accessories changes above implemented in the modified FLOW-i Anesthesia System version 4.2 change the technology or performance of the FLOW-i Anesthesia System.

Conclusion for Substantial Equivalence:
Maquet believes that these modifications do not affect the intended use of the device, the indications for use nor raise any new type of questions of safety and effectiveness.
Maquet has conducted the risk analysis and performed the 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 of the FLOW-i Anesthesia System. Maquet has concluded that the modified FLOW-i Anesthesia System is substantially equivalent to the predicate device, FLOW-i Anesthesia System (K133958).

SUBSTANTIAL EQUIVALENCE TABLE

Specifications from FLOW-i User´s Manual, section 13 Technical Specifications, and: software and hardware changes

	Predicate Device	***SUBJECT DEVICE***
Device	**FLOW-i Anesthesia System version 3.0**	**FLOW-i Anesthesia System version 4.2**
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**
Device Classification Name	Gas-Machine, Anesthesia	Gas-Machine, Anesthesia
510(k) Number	K133958	K160665
Indications for Use according to the 510(k) Summary	The indication for FLOW-i 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.	Same
Patient range	Neonatal to adult patient populations	Same
Settings (adjustable parameters):		
Ventilation Modes	● Manual Ventilation ● Volume Control ● Pressure Control ● Pressure Support + backup ● Pressure Regulated Volume Control (PRVC) ● SIMV	Same
SIMV rate (b/min)	1 – 60	Same
Backup rate (b/min)	2 – 60	Same
Fresh gas oxygen conc	21 – 100 % when Oxygen/Air is selected 28 – 100 % when Oxygen/Nitrous Oxide is selected. Accuracy: 21 – 59%: ±3 % v/v 60-100%: ±5 % v/v	Same
Isoflurane conc	0 – 5 %. Accuracy: ±15% of set value or ±5% of maximum possible setting (whichever is greater)	Same
Sevoflurane conc	0 – 8 %. Accuracy: ±15% of set value or ±5% of maximum possible setting (whichever is greater)	Same
Desflurane conc	0-10%: for set Fresh Gas Flow less than 20 l/min and maximal Fresh Gas Flow less than 75 l/min 0-18%: for set Fresh Gas Flow less than 10 l/min and maximal Fresh Gas Flow less than 40 l/min Accuracy: ±15% of set value or ±5% of maximum possible setting (whichever is greater)	Same
Fresh gas flow	0.3 – 20 l/min Accuracy: ± 10 % or ± 50 ml/min (whichever is greater)	Same
Tidal volume	100 – 2000 ml in the adult patient category. 20 – 350 ml in the infant patient category. Accuracy: ±15% or 10 ml, whichever is greater	Same
Minute volume	0.5 – 60 l/min in the adult patient category. 0.3 – 20 l/min in the infant patient category. Accuracy: ±10% or 10 ml, whichever is greater	Same
PEEP (positive end expiratory pressure)	0 – 50 cmH2O Accuracy: ±2 cmH2O or ±10 % (whichever is greater	Same
Pressure level above PEEP	0 to 120 cmH2O – PEEP in the adult patient category. 0 to 80 cmH2O – PEEP in the infant patient category. Accuracy: ±15 % or ± 2 cmH2O (whichever is greater)	Same

	Predicate Device	***SUBJECT DEVICE***
Device	**FLOW-i Anesthesia System version 3.0**	**FLOW-i Anesthesia System version 4.2**
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**
Breathing frequency	4 – 100 breaths per minute. Accuracy: ±5 % or ± 1 bpm (whichever is greater)	Same
Inspiration and Expiration ratio; I:E	1:10 – 4:1 in automatic modes	Same
Monitoring Measurement range and accuracy:		
Pressure	-30 cmH2O – 140 cmH2O Accuracy: ±5% or ±2 cm H_2O (whichever is greater)	Same
Oxygen conc	0 to 100% Accuracy: ±1 vol% @ (0-25%) ±2 vol% @ (25 – 80%) ±3 vol% @ (80-100%)	Same
Tidal volume	Exp. Tidal volume: Measurement range: 5-2000 ml Accuracy: ± 4ml (5-20 ml) ±10% or 10 ml, whichever is greater (20-2000ml)	Same
Carbon dioxide conc	0 to 10% Accuracy: ± 0.1 vol% @ (0-1%) ± 0.2 vol% @ (1-5%) ± 0.3 vol% @ (5-7%) ± 0.5 vol% @ (7-10%)	Same
Isoflurane conc	0 to 5% Accuracy: ± 0.15 vol% @ (0-1%) ± 0.2 vol% @ (1-5%)	Same
Sevoflurane conc	0 to 8% Accuracy: ± 0.15 vol% @ (0-1%) ± 0.2 vol% @ (1-5%) ± 0.4 vol% @ (5-8%)	Same
Desflurane conc	0 to 18% Accuracy: ± 0.15 vol% @ (0-1%) ± 0.2 vol% @ (1-5%) ± 0.4 vol% @ (5-10%) ± 0.6 vol% @ (10-15%) ± 1.0 vol% @ (15-18%)	Same
Alarms:		
Airway pressure: High	16 to 120 cmH_2O	**10 to 120 cmH_2O**
Software and hardware changes		
US outlets	Not available	**Available**
Recommended ventilation values (PBW)	Not available	**New software functionality**
Airway resistance measurement following an Inspiratory and/or Expiratory Hold	Not available	**New measurement**