K133958

510(k) SUMMARY

MAR 2 0 2014

SUMMARY
as required by section 807.92

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Date prepared: 12/20/2013

Trade Name :	**Model:**	**Model no:**
FLOW-i Anesthesia System	FLOW-i C20	66 77 200
	FLOW-i C30	66 77 300
	FLOW-i C40	66 77 400

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	K112114

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

The modified FLOW-i Anesthesia System version 3.0 is an 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:

- Removal of the Control Gas Analyzer (CGA)
- Measured Tidal Volume lower range in Pressure Control extended
- Inspiratory and Expiratory Hold (Software functionality)
- Apnea Mute (Software functionality)
- HLM Mode (Software functionality)
- O_2Guard Safety function (Software functionality)
- Volume Reflector Indicator (Software functionality)

Non-clinical Testing and Performance

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. The following characteristics of FLOW-i Anesthesia System were thoroughly 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 3.0 consist of:

- Requirement verification of affected requirements
- Regression testing
- Free User Testing (FUT)
- Code review and static code analysis
- Verification of applicable product standards
    - IEC 60601-1
    - IEC 60601-1-1
    - IEC 60601-1-2
    - IEC 60601-1-8
    - IEC 60601-2-13
    - ISO 5356-1
    - ISO5360
    - ASTM F1101-90
    - CGA V-5

Design validation has been performed for each market requirement for FLOW-i Anesthesia System in order to assure the product meets its intended use and user needs, including usability.

Clinical Investigation

The functionality added in the proposed FLOW-i Anesthesia System version 3.0 (K133958) 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 3.0 (K133958) is identical to the predicate device, FLOW-i Anesthesia System version 2.1 (K112114).

Comparison of Technology Used
The technological characteristics for the modified FLOW-i Anesthesia System version 3.0 (K133958) is identical to the predicate device, FLOW-i Anesthesia System version 2.1 (K112114).

Similarities and differences
The main improvements introduced in the modified FLOW-i Anesthesia System version 3.0 (K133958) from the predicate device FLOW-i Anesthesia System version 2.1 (K112114) are:

Removal of the Control Gas Analyzer (CGA)
The Control Gas Analyzer (CGA) in the fresh gas channel was removed in the modified FLOW-i Anesthesia System version 3.0 (K133958). In the predicated device FLOW-i Anesthesia System version 2.1 (K112114) the CGA was used to supervise the vaporizer.

In system version 3.0, the vaporizer has been improved to secure the agent delivery. This, together with some minor and complimentary functions of the Patient Gas Analyzer (PGA) in supervising the agent concentration, will ensure the system's safety and reliability and in turn makes the CGA redundant.

The FLOW-i Anesthesia System uses safety measures at different levels. After removal of the CGA (previously the third of four layers) the safety system consists of three layers with varying responsiveness and accuracy:

- The first layer (**Vaporizer**) supervises the functions in the vaporizer and detects major errors in the Anesthesia Agent (AA) delivery, such as a continuous spray of AA from the injector. The fastest detection of errors occurs in the vaporizer.
- The second layer (**Monitor**) supervises the communication between the control node and the vaporizer. This layer is also very fast.
- The third layer (**Gas analyzer**) samples patient gas at the y-piece and supervises the delivered AA-, and oxygen concentration to the patient using the Patient Gas Analyzer (PGA). This is the most accurate and direct part of the safety system, but also the slowest.

In system version 3.0, the responsibility of the CGA to supervise the gas concentrations was transferred to the Vaporizers and the Patient Gas Analyzer (PGA). This change will not be noticed by the user.

This change will not affect the performance of the FLOW-i Anesthesia System.

Measured Tidal Volume lower range in Pressure Control extended

In the modified FLOW-i Anesthesia System version 3.0 (K133958) the lower range of the measured Tidal Volume in ventilation mode Pressure Control is extended from 20 ml to 5 ml which will allow the user to view a measured value on the control panel for Tidal Volumes between 5-2000 ml. In the predicated device FLOW-i Anesthesia System version 2.1 (K112114) the user can view a measured value on the control panel for Tidal Volumes between 20-2000 ml. This change is for measuring of the Tidal Volume.

Inspiratory and Expiratory Hold (Software functionality)

In the modified FLOW-i Anesthesia System version 3.0 (K133958) a new feature was added which allows the user to hold the patient's breathing cycle at inspiration or expiration and gives the user a lung mechanics measurement tool for static compliance as well as total PEEP.

Apnea Mute (Software functionality)

Induction and some other procedures might warrant the possibility to turn off the audio signal of alarms associated with breathing and breathing parameters. In the modified FLOW-i Anesthesia System version 3.0 (K133958) a new Apnea Mute function which enables the possibility to mute the Apnea related alarms to reduce the stress from annoying audible alarms was added.

HLM Mode (Software functionality)

During open-heart surgery the Heart-Lung Machine (HLM) takes over the patient blood perfusion. During HLM (CardioPulmonary Bypass – CPB) patient related audio alarms are often activated by the anesthesia machine which unintentionally disturbs the surgeon and the operation staff. To avoid the audio disturbance the HLM mode which enable the possibility to set applicable alarms to audio off was added in the modified FLOW-i Anesthesia System version 3.0 (K133958).

O_2Guard Safety function (Software functionality)

In the modified FLOW-i Anesthesia System version 3.0 (K133958) a new hypoxic function was added to support the user to avoid hypoxic gas mixtures from being supplied to the patient. When Oxygen/AIR gas mixture is used and the system detects that the fraction of inspired oxygen (FiO_2) is below a certain threshold the system will automatically adjust the fresh gas flow and the oxygen concentration to predefined fixed levels. A dialog window appears informing of the alterations.

Volume Reflector Indicator (Software functionality)

In the modified FLOW-i Anesthesia System version 3.0 (K133958) the Volume Reflector Indicator (VRI) option was added. The VRI is a graphic representation which visualizes the volume reflector activity and re-breathing fraction.

- The VRI is a graphic representation of the ratio of reflector gas to exhaled gas in the volume reflector.
- The VR balance is a numerical value that describes the net flow of gas in the volume reflector.
- The RBF (Rebreathing Fraction) is a metric that describes how much of the exhaled gas is being re-used during each successive breath.

Other minor modifications to the FLOW-i Anesthesia System 3.0 (K133958) consist of:

- Software upgrades:
  - Graphical User Interface (GUI) improvements.
  - Addition of short trend tab
    The short trend tab depicts waveform data going back 10, 30 or 60 minutes.
  - Inlet pressure on the main display
    Addition of possibility to display the inlet pressure on the main display.
  - Remote Services functionality
    Addition of ability to transfer functionality status information and technical logs to a service remote server.
  - Software changes to handle component replacement due to Last Time Buy and implementation of the RoHS (Restriction of Hazardous Substances) EU directive as well as correction of software anomalies.

None of the modifications above implemented in the modified FLOW-i Anesthesia System version 3.0 changes the technology or performance of the FLOW-i Anesthesia System.

- Labeling changes:
  - Specification change for lower measured Tidal Volume limit from 20 ml to 5 ml.
  - Product label updated with symbol for CSA and IPx1.
  - Addition of Sevoflurane of brand Piramal. The Sevoflurane Vaporizer is also approved for use with the brand Piramal.

None of the labeling changes above implemented in the modified FLOW-i Anesthesia System version 3.0 changes the technology or performance of the FLOW-i Anesthesia System.

- Hardware/Accessories changes:
  - System Checkout valve inserted.
  - Addition of FLOW-i Remote services adaptor.
  - New accessories and modification to existing accessories:
    - Addition of EVAC restrictor
      The EVAC restrictor reduces the flow between high evacuation systems and the FLOW-i AGS outlet (Anesthesia Gas Scavenging outlet) to ensure proper gas evacuation.

    - Addition of Vaporizer Holder
      A holder for a third Vaporizer for easy access to an additional vaporizer during surgical procedures.

    - Addition of Vaporizer slot cover
      The vaporizer slot cover is intended to protect the gas and electrical connections inside the vaporizer slot when no vaporizer is connected and to make the cleaning easier.

    - Addition of Universal bracket C20 for right side
      The Universal bracket is an accessory which supports additional space for mounting of accessory equipment, e.g. a desktop PC or patient monitor power transformer.
      The FLOW-i Anesthesia System C20 already includes a Universal bracket for mounting on the rear side. This version will be for mounting on the right side of the FLOW-i Anesthesia System.

    - Addition of Manual breathing bag rigid support arm
      The support arm is used to provide a static and secure support for the manual breathing bag and associated tubings. The support arm is fastened to the vertical railing on the core unit of the FLOW-i.

    - Redesign of the Gas Backup system for oxygen/air and oxygen/nitrous oxide
      The backup gas system acts as a reserve system if the central gas supply would be unavailable. The FLOW-i C20 and C30 can be equipped with a backup system configured to deliver either oxygen/air or oxygen/nitrous oxide. The redesign of the current backup system includes removal of the wheels and a smother holder. The backup system, gas hoses and cable is as the current system permanently attached to the Core unit of the FLOW-i Anesthesia System.

None of the hardware/accessories changes above implemented in the modified FLOW-i Anesthesia System version 3.0 change the technology or performance of the FLOW-i Anesthesia System.

The modified FLOW-i Anesthesia System version 3.0 (K133958) is an enhancement of the predicate device FLOW-i Anesthesia System version 2.1 (K112114) with the above listed changes/modifications included.

Conclusion for Substantial Equivalence

MAQUET believes these modifications do not affect the intended use of the device, the indications for use nor alter the fundamental scientific technology of the device.

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 version 3.0 (K133958) is substantially equivalent to the predicate device, FLOW-i Anesthesia System version 2.1 (K112114).

SUBSTANTIAL EQUIVALENCE TABLE

Table 1: Specifications from FLOW-i User's Manual, section 14 Technical Specifications.

	Predicate Device	***SUBJECT DEVICE***
Device	**FLOW-i Anesthesia System version 2.1**	**FLOW-i Anesthesia System version 3.0**
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**
Device Classification Name	Gas-Machine, Anesthesia	Gas-Machine, Anesthesia
510(k) Number	K112114	K133958
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):	[redacted]	[redacted]
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

	Predicate Device	*SUBJECT DEVICE*
Device	**FLOW-i Anesthesia System version 2.1**	**FLOW-i Anesthesia System version 3.0**
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**
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: ±10% 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 0.3 l/min (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
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: 20-2000 ml Accuracy: ±10% or 10 ml, whichever is greater	Exp. Tidal volume: **Measurement range: 5-2000 ml** Accuracy: **± 4ml (5-20 ml)** ±10% or 10 ml, whichever is greater (20-2000ml)

	Predicate Device	*SUBJECT DEVICE*
Device	**FLOW-i Anesthesia System version 2.1**	**FLOW-i Anesthesia System version 3.0**
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**
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

Table 2, software and hardware changes

	Predicate Device	*SUBJECT DEVICE*
Device	**FLOW-i Anesthesia System version 2.1**	**FLOW-i Anesthesia System version 3.0**
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**
Device Classification Name	Gas-Machine, Anesthesia	Gas-Machine, Anesthesia
510(k) Number	K112114	K133958
Control Gas Analyzer (CGA)	Available	Removed
Inspiratory and Expiratory Hold option	Not available	New software functionality
Apnea Mute	Not available	New software functionality
HLM (CPB) Mode	Not available	New software functionality
Volume Reflector Indicator (VRI)	Not available	New software functionality
O2 Guard Safety Function	Not available	New software functionality
EVAC restrictor	Not available	New accessory
Vaporizer holder	Not available	New accessory
Vaporizer cover	Not available	New accessory
Universal holder C20 for right side	Not available	New accessory
Manual Breathing bag rigidsupport arm	Available	New shape and fastening
Gas Backup system O_2/Air or O_2/N_2O	Available	Redesigned

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Maquet Critical Care AB
C/O Lia Liebgold
Regulatory Affairs Specialist
Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K133958
Trade Name: Maquet FLOW-i Anesthesia System, Models C20, C30 and C40
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: January 10, 2014
Received: January 13, 2014

Dear Ms. Liebgold:

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.

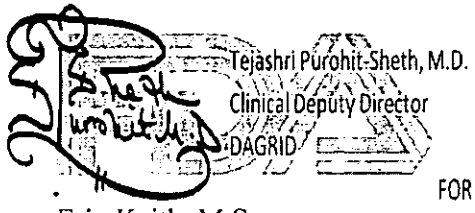
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



FOR

Erin Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133958

Device Name
FLOW-i Anesthesia System

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Todd D. Courtney -S
2014.03.18 10:30:32 -04'00'

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