



January 12, 2018

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Yanhong Bai
Manager Regulatory Affairs, Technical Regulation Department
Mindray Builday, Keji 12th Road South,
Hi-tech Industrial Park,
Shenzhen, 518057 China

Re: K171311

Trade/Device Name: A5 Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ, CCK, NHO, CBQ, NHQ, NHP, CBS, CBR, CCL
Dated: December 8, 2017
Received: December 11, 2017

Dear Yanhong Bai:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -
S

Digitally signed by Tara A. Ryan -
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Tara A. Ryan -
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Date: 2018.01.12 09:06:21 -0500

Tina Kiang, Ph.D.
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)

K171311

Device Name

A5 Anesthesia System

Indications for Use (Describe)

The A5 Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

The A5 is intended for use by licensed clinicians, for patients requiring anesthesia within a health care facility, and can be used in adult and pediatric (including neonate, infant, child and adolescent) populations.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the A5 Anesthesia System is provided below.

Device Common Name: Gas-Machine, Anesthesia

Device Proprietary Name: A5 Anesthesia System

Submitter: SHENZHEN MINDRAY BIO-MEDICAL
ELECTRONICS CO., LTD.
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Date Prepared: December 6th, 2017

Panel: Anesthesiology

Classification Regulation and Product Code:

Primary:
868.5160- BSZ Anesthesia Gas Machine Class II

Secondary:
868.1400 – CCK - Carbon Dioxide Gas Analyzer
868.1500 – NHO/CBQ/NHQ/NHP - Enflurane gas analyzer
868.1620 – CBS - Halothane Gas Analyzer
868.1700 – CBR - Nitrous Oxide Gas Analyzer
868.1720 – CCL- Oxygen Gas Analyzer

Predicate Device:

510(k) number	Trade or proprietor or model name	Manufacturer
K123211	A5 Anesthesia Delivery System	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Reference Devices:

510(k) number	Trade or proprietor or model name	Manufacturer
K151954	A7 Anesthesia System	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
K083050	Evita XL Ventilator	Dräger Medical AG & Co. KG
K110213	GE Datex-Ohmeda Aisys	Datex-Ohmeda Inc.
K132530	GE Datex-OhmedaAisys CS ²	Datex-Ohmeda Inc.

Indication for Use:

The A5 Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

The A5 is intended for use by licensed clinicians, for patients requiring anesthesia within a health care facility, and can be used in adult and pediatric (including neonate, infant, child and adolescent) populations.

Device Description:

The A5 Anesthesia System is a continuous flow inhalation gas anesthesia system that delivers anesthetic vapor and provides for automatic and manual modes of ventilation. The A5 incorporates O₂, CO₂, N₂O and Agent concentration monitoring (Desflurane, Isoflurane, Enflurane, Sevoflurane and Halothane).

Nonclinical testing and Performance:

The following areas have been tested:

- Software
 - Unit testing
 - Integration testing
 - System testing
- Performance

- Power Supply
- Thermal
- Cleaning and Disinfection
- Fresh Flow Optimizer
- AG Module
- Heating Module
- Waveform Comparison
- Biocompatibility
 - Volatile Organic Compounds
 - Particulate Testing
 - Cytotoxicity
 - Sensitization
 - Irritation / intracutaneous reactivity
 - Extractables and leachables (E&L) testing
 - Inorganic gases (O3, O2, CO2, NO2) testing
- Human Factors Validation Testing
- Testing as per consensus standards:
 - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General Requirements for basic safety and essential performance
 - IEC 60601-1-2 Edition 3: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
 - ISO 80601-2-13 First edition 2011-08-11 Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anesthetic workstation
 - ISO 80601-2-55 First edition 2011-12-15 Medical electrical equipment -Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
 - ASTM F1101-90 (Reapproved 2003) Standard Specification for Ventilators Intended for Use During Anesthesia

 - AIM 7351731 medical electrical equipment and system electromagnetic immunity test for exposure to radio frequency identification readers - an aim standard. (General II (ES/EMC))

The functional and system level testing showed that the device continues to meet specifications and the performance of the device is equivalent to the predicate.

Substantial Equivalence:

Comparison of Indications

Both the predicate device and the subject A5 Anesthesia System are gas anesthesia machine used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. The indications for use of the subject device (A5 Anesthesia System) have been modified to add the definition of the pediatric population subgroup. All of the pediatric population subgroup was cleared in the predicate device A5 Anesthesia Delivery System (K123211). In conclusion, the minor changes to the indications for use do not change the intended use of the A5 Anesthesia System.

Comparison of Technological Characteristics:

The table below compares the key technological feature of the subject device to the predicate device (A5 Anesthesia Delivery System (K123211)).

Device Comparison Table

Technical Characteristics		Subject Device A5 Anesthesia System	Predicate Device A5 Anesthesia Delivery System (K123211)
Vaporizers		Two or Three, variable bypass	Two or three, variable bypass
Agent - Sevoflurane		Yes	Yes
Agent – Isoflurane		Yes	Yes
Agent – Desflurane		Yes	Yes
Agent – Halothane		Yes	Yes
Agent - Enflurane		Yes	Yes
Automatic Ventilator		Yes	Yes
Bellows		Yes	Yes
Bellows Volume		1500mL	1500mL
<i>Ventilation Modes</i>			
VCV		Yes	Yes
PCV		Yes	Yes
PCV-VG		Yes	Yes
SIMV-VC		Yes	Yes
SIMV-PC		Yes	Yes
PS		Yes	Yes
<i>Specifications</i>			
Tidal Volume		Yes	Yes
Range, ml		20 to 1500	20 to 1500
Minute Volume		Yes	Yes
Rate, bpm		4 to 100 bpm	4 to 100 bpm
I:E Ratio		4:1 to 1:8 with 0.5 increment	4:1 to 1:8 with 0.5 increment
Inspiratory Pause		Off, 5 to 60% of insp. Period	Off, 5 to 60% of insp. Period
Fresh Gas	Air Flow Range	0 to 15 L/min	0 to 15 L/min
	N ₂ O Flow Range	0 to 12 L/min	0 to 12 L/min
	O ₂ Flow Range	0 to 15 L/min	0 to 15 L/min

Technical Characteristics		Subject Device A5 Anesthesia System	Predicate Device A5 Anesthesia Delivery System (K123211)
	Individual Gas Flow Accuracy	±50 ml/min or ±5% of setting value, whichever is greater	±50 ml/min or ±5% of setting value, whichever is greater
	Pressure Limit, cm H ₂ O	0 to 100 cm H ₂ O	0 to 100 cm H ₂ O
	PEEP, cm H ₂ O	Off, 3 to 30, 1 cm H ₂ O increment	Off, 3 to 30, 1 cm H ₂ O increment
	System Checks	Auto at start	Auto at start
	Airway Pressure Measured at	Inspiratory	Inspiratory
	High/Low Airway Pressure Alarm	Yes	Yes
	Pressure Limiting Alarm	Yes	Yes
	Sub Atmospheric Pressure Alarm	Yes	Yes
	Continuous Press Alarm	Yes	Yes
	Apnea >2 Minute Alarm	Yes	Yes
	Apnea Alarm	Yes	Yes
	High/Low Minute Volume Alarm	Yes	Yes
	High/Low O ₂ Concentration Alarm	Yes	Yes
	Type of O ₂ Sensor	Paramagnetic or Galvanic fuel cell	Paramagnetic or Galvanic fuel cell
	Heated Breathing Circuit	Yes	Yes
	Spirometry: Pressure-Volume and Flow-Volume loops	Yes	Yes
	Anesthetic Gas Module Sampling Rate	Adult/pediatric: 120, 150, 200 mL/min Neonate: 70, 90, 120 mL/min	High volume: 120, 150, 200 mL/min Low volume: 70, 90, 120 mL/min
	Anesthetic Gas Module Sampling Delay Time:	<4 seconds	<4 seconds
	Anesthetic Gas Module Refresh Rate:	1 second	1 second
	Anesthetic Gas Module Warm-up Time:	45 seconds to warm-up status 10 minutes to ready-to-measure status	45 seconds to warm-up status 10 minutes to ready-to-measure status
	Anesthetic Gas Module Accuracy CO ₂ :	0 to 1%: +/- .1% 1 to 5%: +/- .2% 5 to 7%: +/- .3% 7 to 10%: +/- .5% >10%: unspecified	0 to 1%: +/- .1% 1 to 5%: +/- .2% 5 to 7%: +/- .3% 7 to 10%: +/- .5% >10%: unspecified

Technical Characteristics	Subject Device A5 Anesthesia System	Predicate Device A5 Anesthesia Delivery System (K123211)
Anesthetic Gas Module Accuracy N ₂ O:	0 to 20%: +/-2% 20 to 100%: +/-3%	0 to 20%: +/-2% 20 to 100%: +/-3%
Anesthetic Gas Module Accuracy Desflurane:	0 to 1%: +/-15% 1 to 5%: +/-2% 5 to 10%: +/-4% 10 to 15%: +/-6% 15 to 18%: +/-1% >18%: unspecified	0 to 1%: +/-15% 1 to 5%: +/-2% 5 to 10%: +/-4% 10 to 15%: +/-6% 15 to 18%: +/-1% >18%: unspecified
Anesthetic Gas Module Accuracy Sevoflurane:	0 to 1%: +/-15% 1 to 5%: +/-2% 5 to 8%: +/-4% >8%: unspecified	0 to 1%: +/-15% 1 to 5%: +/-2% 5 to 8%: +/-4% >8%: unspecified
Anesthetic Gas Module Accuracy Enflurane/Isoflurane/ Halothane:	0 to 1%: +/-15% 1 to 5%: +/-2% >5%: unspecified	0 to 1%: +/-15% 1 to 5%: +/-2% >5%: unspecified
Anesthetic Gas Module Accuracy O ₂ :	0 to 25%: +/-1% 25 to 80%: +/-2% 80 to 100%: +/-3%	0 to 25%: +/-1% 25 to 80%: +/-2% 80 to 100%: +/-3%
Anesthetic Gas Module Accuracy awRR:	2 to 60rpm: +/-1rpm >60rpm: unspecified	2 to 60rpm: +/-1rpm >60rpm: unspecified
Anesthetic Gas Module Measurement Rise Time:	CO ₂ : ≤250ms N ₂ O: ≤250ms O ₂ : ≤500ms Hal/Iso/Sev/Des: ≤300ms Enf: ≤350ms	CO ₂ : ≤250ms N ₂ O: ≤250ms O ₂ : ≤500ms Hal/Iso/Sev/Des: ≤300ms Enf: ≤350ms
Measurement Range CO ₂	0 to 30%	0 to 30%
Measurement Range N ₂ O	0 to 100%	0 to 100%
Measurement Range Des	0 to 30%	0 to 30%
Measurement Range Sev	0 to 30%	0 to 30%
Measurement Range Enf/Iso/Hal	0 to 30%	0 to 30%
Measurement Range O ₂	0 to 100%	0 to 100%

There are some differences between the subject A5 Anesthesia System and the predicate device A5 Anesthesia Delivery System (K123211). Per the FDA Guidance, “*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*” issued July 28, 2014, the following devices are provided to support substantial equivalence.

Differences from Predicate Device A5 (K123211)

Differences		Reference Device
Add Three Ventilation Modes	SIMV-VG	Evita XL Ventilator (K083050)
	CPAP/PS	Aisys anesthesia system (K110213)
	APRV	Evita XL Ventilator (K083050)
Lung Recruitment Ventilation Function		GE Datex-Ohmeda Aisys CS ² Anesthesia System (K132530)
Optimizer Function and Agent Usage Calculation Function		A7 Anesthesia System (K151954)
Redesign the Existing Ventilator Control Board Using DSP Hardware Platform		A5 Anesthesia Delivery System (K123211)
Change about the Anesthetic Gas Module and Accessories		A5 Anesthesia Delivery System (K123211)
Get Data from Anesthetic Gas Module plugged into the Passport 12M/17M patient monitor (K170876) to support optimizer function and agent usage calculation function		A7 Anesthesia System (K151954)
Increase the Maximum Inspiratory Flow		Evita XL Ventilator (K083050)
Change the Material of the Airway Pressure Gauge Housing		A7 Anesthesia System (K151954)

Substantial Equivalence Conclusion

Based on the detailed comparison of specifications for each of the modifications to the previously cleared A5 Anesthesia Delivery System (K123211) and cited reference devices, the performance testing results and conformance with applicable standards show that the A5 Anesthesia System can be found substantially equivalent to the predicate device.