January 12, 2018

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

Re: K171292
Trade/Device Name: A7 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, CBS, CBQ, CBR, CCL, NHQ, NHP, KDP
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 -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tara A. Ryan -S, 0.9.2342.19200300.100.1.1=1300030749
Date: 2018.01.12 11:26:05 -05'00'

for
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

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)*
K171292

Device Name
A7 Anesthesia System

Indications for Use *(Describe)*
The A7 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 A7 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the A7 Anesthesia System is provided below:

Device Common Name: Gas-Machine, Anesthesia

Device Proprietary Name: A7 Anesthesia System

Submitter: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South
High-tech Industrial Park, Nanshan
Shenzhen 518057, P.R. China
Tel: +86 755 81885635
Fax: +86 755 26582680

Contact: Yanhong Bai
Manager Regulatory Affairs
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South
High-tech Industrial Park, Nanshan
518057, P.R. China
Tel: +86 755 81885635
Fax: +86 755 26582680
E-mail: baiyanhong@mindray.com

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

880.6740 – KDP- Vacuum Regulator

Predicate Device:

510(k) number	Trade or proprietor or model name	Manufacturer
K151954	A7 Anesthesia System	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Reference Devices:

510(k) number	Trade or proprietor or model name	Manufacturer
K123211	A5 Anesthesia Delivery System	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
K083050	Evita XL Ventilator	Dräger Medical AG & Co. KG
K110213	GE Datex-OhmedaAisys	Datex-Ohmeda Inc.
K132530	GE Datex-OhmedaAisys CS^2	Datex-Ohmeda Inc.

Indications for Use:

The A7 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 A7 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 A7 Anesthesia System is a continuous flow inhalation gas anesthesia system that delivers anesthetic vapor and provides for automatic and manual modes of ventilation. The A7 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
    - AG Module
    - Fresh Flow Optimizer
    - Sample Gas Return and CO2-absorbent

  - Suction
  - Heating Module
  - Power Supply
  - Thermal
  - Cleaning and Disinfection
  - 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
  - ISO 10079-3:2014 Medical suction equipment — Part 3:Suction equipment powered from a vacuum or positive pressure gas source
  - 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 A7 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 (A7 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 A7 Anesthesia System (K151954). In conclusion, the minor changes to the indications for use do not change the intended use of the A7 Anesthesia System.

Comparison of Technological Characteristics:

The table below compares the key technological feature of the subject device to the predicate device (A7 Anesthesia System (K151954)).

Device Comparison Table

Technical Characteristics		Subject Device A7 Anesthesia System (subject device)	Predicate Device A7 Anesthesia System (K151954)
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
Ventilation Modes			
VCV		Yes	Yes
PCV		Yes	Yes
PCV – VG		Yes	Yes
SIMV – VC		Yes	Yes
SIMV – PC		Yes	Yes
PS		Yes	Yes
Specifications			
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_2O 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 A7 Anesthesia System (subject device)	Predicate Device A7 Anesthesia System (K151954)
	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_2O		0 to 100cm H_2O	0 to 100cm H_2O
PEEP, cm H_2O		Off, 3 to 30, 1 cm H_2O increment	Off, 3 to 30, 1 cm H_2O 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
Heated Breathing Circuit		Yes	Yes
Spirometry: Pressure-Volume and Flow-Volume loops		Yes	Yes
Anesthetic Gas Module Sampling Rate		Adult/pediatric: 120, 150, 200mL/min Neonate: 70, 90, 120mL/min	High volume: 120, 150, 200mL/min Low volume: 70, 90, 120mL/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 to10%: +/-.5% >10%: unspecified	0 to 1%: +/-.1% 1 to 5%: +/-.2% 5 to 7%: +/-.3% 7 to10%: +/-.5% >10%: unspecified
Anesthetic Gas Module Accuracy N_2O:		0 to 20%: +/-2% 20 to 100%: +/-3%	0 to 20%: +/-2% 20 to 100%: +/-3%

Technical Characteristics	Subject Device A7 Anesthesia System (subject device)	Predicate Device A7 Anesthesia System (K151954)
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_2O: ≤250ms O_2: ≤500ms Hal/Iso/Sev/Des: ≤300ms Enf: ≤350ms	CO_2: ≤250ms N_2O: ≤250ms O_2: ≤500ms Hal/Iso/Sev/Des: ≤300ms Enf: ≤350ms
Measurement Range CO_2	0 to 30%	0 to 30%
Measurement Range N_2O	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 A7 Anesthesia System and the predicate device A7 Anesthesia System (K151954). 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		**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)
Added O2 Sensor		A5 Anesthesia Delivery System (K123211)
Redesign the Existing Ventilator Control Board Using DSP Hardware Platform		A7 Anesthesia System (K151954)
Change about the Anesthetic Gas Module and Accessories		A7 Anesthesia System (K151954)
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 A7 Anesthesia System (K151954) and cited reference devices, the performance testing results and conformance with applicable standards show that the A7 Anesthesia System can be found substantially equivalent to the predicate device.