DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 23, 2015

Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Tang Hao
Product Approval Engineer, Technical Regulation Department
Mindray Building, Keji 12th Road South
High-tech Industrial Park, Nanshan
Shenzhen, Guandong 518057
CHINA

Re: K142552
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
Dated: December 19, 2014
Received: December 22, 2014

Dear Mr. Hao,

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
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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)*
K142552

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 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)

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)*

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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 A7 Anesthesia System is provided below.

Device Common Name: Gas-Machine, Anesthesia

Device Proprietary Name: A7 Anesthesia System

Submitter:
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Date Prepared: January 23, 2015

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 Devices:
K123211 - A5 Anesthesia Delivery System, Mindray DS USA, Inc.
K042607 - Primus US, Draeger Medical Inc.
K110213 - GE Datex-Ohmeda Aisys, Datex-Ohmeda Inc.

K123125 – Avance CS2, GE

Indication 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 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 O_2, CO_2, N_2O and Agent concentration monitoring (Desflurane, Isoflurane, Enflurane, Sevoflurane and Halothane). The A7 consists of a main unit (includes an anesthetic ventilator and flow meter monitor assembly) and a detachable breathing system.

Performance Data:

Biocompatibility – Each patient contacting material and gas path material has been tested to comply with the following applicable requirements per ISO 10993-1:

- **Cytotoxicity:** ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- **Irritation:** ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- **Sensitization**: ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- **Volatile Organic Compound Testing**: ISO10993-18:2005 Biological evaluation of medical devices -- Part 18: Chemical characterization of materials

Software – The A7 Anesthesia System software has been fully verified and validated and documentation in accordance with FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: May 11, 2005" has been provided in this submission.

Performance Testing – The A7 Anesthesia system has been tested to comply with its product specifications and intended use. The following standards were adhered to for performance testing:

- IEC 60601-1:1988+A1:1991+A2:1995: Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-1:2000 General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:2000 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems

- IEC 60601-1-8:2003 Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-13:2009 Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anesthetic systems
- IEC 62304: 2006 Medical device software - Software life cycle processes
- IEC 62366:2007 Medical devices - Application of usability engineering to medical devices
- ISO 14971:2007 Medical devices - Application of risk management to medical devices
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements
- ISO 5356-1:2004 Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
- ISO 21647:2004 Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ASTM F1101-90:2003 Standard Specification for Ventilators Intended for Use During Anesthesia
- CGA V-1:2005 Standard for Compressed Gas Cylinder Valves Outlet and Inlet Connections
- CGA V-5:2008 Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)

Substantial Equivalence:

The subject device has the exact same indication statement as the primary predicate device, the A5 as cleared in K123211. The subject A7 Anesthesia System and the primary predicate are both gas anesthesia machines used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. These systems may be used in adult and pediatric populations. Both of the devices are prescription use, and are not suitable for use in an MRI environment.

A technical comparison of the subject device to the primary predicate device, the A5 as cleared in K123211 is provided in the table below.

Technical Characteristics	**A7 Anesthesia Delivery System** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd**	**A5 Anesthesia Delivery System** **Mindray DS USA, Inc.** **K123211**
Vaporizers	Two, variable bypass	Two, variable bypass
Agent - Sevoflurane	Yes	Yes
Agent – Isoflurane	Yes	Yes

Technical Characteristics		A7 Anesthesia Delivery System Shenzhen Mindray Bio-Medical Electronics Co., Ltd	A5 Anesthesia Delivery System Mindray DS USA, Inc. K123211
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
Tidal Volume		Yes	Yes
Specifications			
Range, ml		20 - 1500	20 - 1500
Minute Volume		Yes	Yes
Rate, bpm		4-100 bpm	4-100 bpm
Inspiratory Flow, L/min		110 L/min + fresh gas flow	110 L/min + fresh gas flow
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 - 60% of insp. Period	Off, 5 - 60% of insp. Period
Fresh Gas	Air Flow Range	0~15 L/min	0~15 L/min
	N_2O Flow Range	0~12 L/min	0~12 L/min
	O_2 Flow Range	0~15 L/min	0~15 L/min
	Individual Gas Flow Accuracy	±50 ml/min or ±5% of setting value, whichever is greater	±120 ml/min or ±10% of setting value, whichever is greater
Pressure Limit, cm H_2O		0 – 100	0 – 100
PEEP, cm H_20		Off, 3-30, 1 cmH2O increment	Off, 3-30, 1 cmH2O increment
System Checks		Auto at start	Auto at start
Airway Pressure Measured at		Inspiratory	Inspiratory
High/Low Airway		Yes	Yes

Technical Characteristics	A7 Anesthesia Delivery System Shenzhen Mindray Bio-Medical Electronics Co., Ltd	A5 Anesthesia Delivery System Mindray DS USA, Inc. K123211
Pressure Alarm		
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	Paramagnetic or Galvanic *(The Paramagnetic sensor is utilized when using the integrated gas module. The Galvanic sensor is utilized when the gas module is not connected.)*
Heated Breathing Circuit	Yes	Yes
Spirometry: Pressure-Volume and Flow-Volume loops	Yes	Yes
Anesthetic Gas Module Sampling Rate	P/N 9200-10-10530 water trap: 120, 150, 200mL/min P/N 9200-10-10574 water trap: 70, 90, 120mL/min	P/N 9200-10-10530 water trap: 120, 150, 200mL/min P/N 9200-10-10574 water trap: 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:	0-1%: +/-.1% 1-5%: +/-.2% 5-7%: +/-.3% 7-10%: +/-.5% >10%: unspecified	0-1%: +/-.1% 1-5%: +/-.2% 5-7%: +/-.3% 7-10%: +/-.5% >10%: unspecified

Technical Characteristics	A7 Anesthesia Delivery System Shenzhen Mindray Bio-Medical Electronics Co., Ltd	A5 Anesthesia Delivery System Mindray DS USA, Inc. K123211
Anesthetic Gas Module Accuracy N_2O:	0-20%: +/-2% 20-100%: +/-3%	0-20%: +/-2% 20-100%: +/-3%
Anesthetic Gas Module Accuracy Desflurane:	0-1%: +/-.15% 1-5%: +/-.2% 5-10%: +/-.4% 10-15%: +/-.6% 15-18%: +/-1% >18%: unspecified	0-1%: +/-.15% 1-5%: +/-.2% 5-10%: +/-.4% 10-15%: +/-.6% 15-18%: +/-1% >18%: unspecified
Anesthetic Gas Module Accuracy Sevflurane:	0-1%: +/-.15% 1-5%: +/-.2% 5-8%: +/-.4% >8%: unspecified	0-1%: +/-.15% 1-5%: +/-.2% 5-8%: +/-.4% >8%: unspecified
Anesthetic Gas Module Accuracy Enflurane/Isoflurane/ Halothane:	0-1%: +/-.15% 1-5%: +/-.2% >5%: unspecified	0-1%: +/-.15% 1-5%: +/-.2% >5%: unspecified
Anesthetic Gas Module Accuracy O_2:	0-25%: +/-1% 25-80%: +/-2% 80-100%: +/-3%	0-25%: +/-1% 25-80%: +/-2% 80-100%: +/-3%
Anesthetic Gas Module Accuracy awRR:	2-60rpm: +/-1rpm >60rpm: unspecified	2-60rpm: +/-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	0-30%	0-30%
Measurement Range N_2O	0-100%	0-100%
Measurement Range Des	0-30%	0-30%
Measurement Range Sev	0-30%	0-30%
Measurement Range Enf/Iso/Hal	0-30%	0-30%
Measurement Range O_2	0-100%	0-100%

Substantial Equivalence Conclusion

There are seven new features that have been added to the A7 when compared to the A5 as follows:

1. Fresh Gas Control System
2. Negative Pressure Suction Device
3. Agent Consumption Calculation
4. Auxiliary Common Gas Outlet
5. Sample Gas Return
6. Quick Release APL Valve
7. Auxiliary Work Surface

A detailed comparison of these 7 new features is provided in the submission and performance testing was completed to establish that the new features do not raise new issues of safety and effectiveness.

The A7 Anesthesia System has the same intended use as the predicate device, to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. The A7 is a line extension of the FDA-cleared A5 Anesthesia System (the primary predicate device), and has the identical indications for use as the A5. The differences in the technological characteristics of these features when compared to the predicate device do not raise new types of safety and effectiveness questions. Therefore the A7 can be found substantially equivalent to the predicate device.