



Food and Drug Administration
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October 27, 2015

Shenzhen Mindray Bio-Medical Electronics Co. LTD
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South
High-tech Industrial Park, Nanshan
518057, P.R China

Re: K151954

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, CBS, CBR, NHO, CBQ,NHQ,NHP, CCL, KDP
Dated: September 23, 2015
Received: September 24, 2015

Dear Mr. 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.

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" (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 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 I. Keith, M.S.
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Division of Anesthesiology, Respiratory General
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Enclosure

Indications for Use

510(k) Number (if known)

K151954

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)

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 A7 Anesthesia System is provided below.

Device Common Name: Gas-Machine, Anesthesia

Device Proprietary Name: A7 Anesthesia System

Submitter: SHENZHEN MINDRAY BIO-MEDICAL
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Date Prepared: July 15, 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:

K142552 – A7 Anesthesia System, ShenZhen Mindray Bio-Medical Electronics CO., LTD.
K042607 - Primus US, Draeger Medical Inc.

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 O₂, CO₂, N₂O 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:

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 submitted in this 510(k):

- ANSI/AAMI ES60601-1:2005/(R) 2012 and C1:2009/(R) 2012 and, A2:2010/(R) 2012 Medical electrical equipment - Part 1: General Requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-8:2006 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-13:Edition 3.1 2009-08 Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anesthetic systems
- ISO 80601-2-55:2011 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC 62304: 2006 Medical device software - Software life cycle processes

Substantial Equivalence:

The A7 that is the subject of this 510(k) submission has been modified from the A7 that was cleared in K142552 to include the Fresh Gas Flow Optimizer feature. The Fresh Gas Flow Optimizer displays a recommended value for fresh gas to assist the clinician in determining a value that will meet the needs of the patient. The predicate device as cleared by FDA did not provide this feature. This feature does not change the fresh gas flow setting nor does it supply an alarm if the user does not follow the recommended fresh gas flow setting.

A technical comparison of the subject device to the primary predicate device as cleared in K142552 is provided in the table below.

Technical Characteristics	Subject Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (Subject Device)	Predicate Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (K142552)
Vaporizers	Two or Three, variable bypass	Two, 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
Tidal Volume	Yes	Yes
<i>Specifications</i>		
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

Technical Characteristics		Subject Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (Subject Device)	Predicate Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (K142552)
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 ₂ O 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 ₂ O		0 – 100	0 – 100
PEEP, cm H ₂ O		Off, 3-30, 1 cmH ₂ O increment	Off, 3-30, 1 cmH 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	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

Technical Characteristics	Subject Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (Subject Device)	Predicate Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (K142552)
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
Anesthetic Gas Module Accuracy N ₂ O:	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

Technical Characteristics	Subject Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (Subject Device)	Predicate Device A7 Anesthesia System <u>ShenZhen Mindray Bio-Medical Electronics CO., LTD.</u> (K142552)
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	0-30%	0-30%
Measurement Range N ₂ O	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

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.

Based on the technical comparison, the identical indications for use and the complete system level testing, the modifications to the A7 Anesthesia System do not raise different questions of safety and effectiveness and can be found substantially equivalent to the predicate device cleared in K142552.