March 26, 2021

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

Re: K201957
Trade/Device Name: A8, A9 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, NHP, CBS, CBR, CCL, KDP, NHQ
Dated: February 24, 2021
Received: February 25, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K201957

Device Name
A8, A9 Anesthesia System

Indications for Use *(Describe)*
The A8, A9 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 A8, A9 is intended for use by licensed clinicians in the administration of general anesthesia, for patients requiring anesthesia within a health care facility, and can be used in adult, pediatric and neonate populations.
High Flow Nasal Cannula (HFNC) is indicated for delivery of nasal high flow oxygen to spontaneously breathing adult patients. It can be used for pre-oxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms. It is not intended for apneic ventilation. HFNC is indicated for use in adults only.

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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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mindray A8, A9 Anesthesia System is provided below.

## 1. SUBMITTER

Applicant: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Contact: Contact Person: Yanhong Bai
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Fax: +86 755 26582680
E-mail: baiyanhong@mindray.com

Date Prepared: March 25, 2021

## 2. DEVICE

Device Trade Name: A8, A9 Anesthesia System

Device Common Name: Gas-Machine, Anesthesia

Classification Name: 868.5160, Class II, Gas-Machine, Anesthesia

Regulatory Class: Class II

Primary Product Code: BSZ

**Table 1: Secondary Product Codes**

| Regulation Number/Class | Product Code | Regulation description | Device Common Name |
|---|---|---|---|
| 868.1400, II | CCK | Carbon Dioxide Gas Analyzer | Carbon Dioxide Gas Analyzer |
| 868.1500, II | NHO/CBQ/NHQ/NHP | Enflurane gas analyzer | Enflurane gas analyzer |

| Regulation Number/Class | Product Code | Regulation description | Device Common Name |
|---|---|---|---|
| 868.1620, II | CBS | Halothane Gas Analyzer | Halothane Gas Analyzer |
| 868.1700, II | CBR | Nitrous Oxide Gas Analyzer | Nitrous Oxide Gas Analyzer |
| 868.1720, II | CCL | Oxygen Gas Analyzer | Oxygen Gas Analyzer |
| 880.6740, II | KDP | Vacuum | Vacuum |

## 3. PREDICATE DEVICES

**Primary predicate:**

- K171292 - A7 Anesthesia System, ShenZhen Mindray Bio-Medical Electronics Co., Ltd.

**Secondary predicate:**

- K192972 - BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1), ShenZhen Mindray Bio-Medical Electronics Co., LTD. (Supports Anesthetic gas module and accessories)

## 4. REFERENCE DEVICES

Per the FDA Guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued July 28, 2104, the following reference devices are provided to support substantial equivalence:

- K160665 - Flow-i Anesthesia System C20, Flow-i Anesthesia System C30, Flow-i Anesthesia System C40, Maquet Critical Care AB (Supports electronic vaporizers, sealed lead acid battery, electronic flowmeter total flow range)
- K151570 - Carestation 620/650/650C, Datex-Ohmeda, Inc. (Supports apnea pressure and trig window, sealed lead acid battery, APL Valve Adjustable Range)
- K083050 - Evita XL Ventilator, Drager Medical AG & Co. KG (Supports tidal volume, Inspiratory pressure, support pressure, Plimit, PEEP, Phigh, Plow, RR, PEEP on Exit)
- K180295- HAMILTON-G5, HAMILTON MEDICAL AG (Supports HFNC)

## 5. DEVICE DESCRIPTION

The A8, A9 Anesthesia System is a continuous flow inhalation gas anesthesia system that delivers anesthetic vapor and provides for automatic and manual modes of ventilation. The A8, A9 Anesthesia System incorporates $O_2$, $CO_2$, $N_2O$ and Agent concentration monitoring (Desflurane, Isoflurane, Halothane, and Sevoflurane). The A8, A9 Anesthesia System is a modified version the previously cleared Mindray A7 Anesthesia System cleared in K171292.

## 6. INTENDED USE/INDICATIONS FOR USE

The A8, A9 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 A8, A9 is intended for use by licensed clinicians in the administration of general anesthesia, for patients requiring anesthesia within a health care facility, and can be used in adult, pediatric and neonate populations.

High Flow Nasal Cannula (HFNC) is indicated for delivery of nasal high flow oxygen to spontaneously breathing adult patients. It can be used for pre-oxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms. It is not intended for apneic ventilation. HFNC is indicated for use in adults only.

## 7. SUBSTANTIAL EQUIVALENCE

### Comparison of Indications

Comparing with the primary predicate A7 Anesthesia System (K171292), the indications for use for the subject device A8, A9 Anesthesia System includes the indications for use for the A7 and additionally adds the indications for use for HFNC in adult patients. As the definition of pediatric population subgroups includes the neonate population according to Table 1 of the FDA Guidance, *"Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices" issued May 14, 2004*, all the populations of the subject device A8, A9 Anesthesia System were cleared in the primary predicate A7 Anesthesia System (K171292).

The BeneVision N Series Patient Monitor modules (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1), ShenZhen Mindray Bio-Medical Electronics Co., LTD cleared under K192972 are incorporated into this workstation with no changes to the modules. This predicate serves as a reference device for the Anesthetic Gas Module. A more detailed comparison of the features is included in the sections below.

The indications for the BeneVision N Series Patient Monitors modules are the same since the modules are incorporated with no changes in indications into the anesthesia workstation.

As a conclusion, the indications for use of the subject device A8, A9 Anesthesia System is the same as the primary predicate A7 Anesthesia System as cleared in K171292 and the BeneVision N Series Patient Monitors cleared in K192972.

### Comparison of Technological Characteristics

The table below compares the key technological feature of the subject devices to the primary predicate device (A7 Anesthesia System (K151954)). The features in gray are features which are different between the predicate devices and the subject devices.

| **Technical Characteristics** | **Subject device**<br>**A8 Anesthesia System**<br><br>**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**<br>**(Subject device)** | **Subject device**<br>**A9 Anesthesia System**<br><br>**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**<br>**(Subject device)** | **Primary predicate**<br>**A7 Anesthesia System**<br><br>**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**<br>**(K171292)** |
|---|---|---|---|
| Connection Type | Double, Selectatec®, with interlocking function | Double, **Insertion type connection, with interlocking function** | Two or three, Selectatec®, with interlocking function |
| Electronic Vaporizer | - | Working with an electronic based injector | - |
| | - | Applicable anesthetic agent:<br>Isoflurane<br>Sevoflurane<br>Desflurane | - |
| | - | Filling method:<br>Isoflurane (Safety filling adapter)<br>Sevoflurane (Safety filling adapter)<br>Sevoflurane (Quik-fil)<br>Desflurane (Saf-T-Fill) | - |
| | - | Setting range:<br>Isoflurane: 0.0% to 5.0%<br>Sevoflurane: 0.0% to 8.0%<br>Desflurane: 0.0% to 18.0% | - |
| | - | Accuracy: ±15% of the setting value or ±5% of the maximum setting value, whichever is greater | - |
| Anesthetic agent - Sevoflurane | Yes | | Yes |
| Anesthetic agent - Isoflurane | Yes | | Yes |
| Anesthetic agent - Desflurane | Yes | | Yes |
| Anesthetic agent - Halothane | Yes | - | Yes |
| ***Working Mode*** | | | |
| Standby mode | Yes | | Yes |
| Manual Ventilation mode | Yes | | Yes |
| Automatic Ventilator mode | Yes | | Yes |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Lung Recruitment Ventilation | Yes | | Yes |
| Cardiac Bypass mode | Yes | | Yes |
| ACGO mode | Yes | | Yes |
| Flow Pause | Yes | | Yes |
| Monitor mode | Yes | | Yes |
| ***Automatic Ventilation mode*** | | | |
| VCV | Yes | | Yes |
| PCV | Yes | | Yes |
| PCV-VG | Yes | | Yes |
| SIMV-VC | Yes | | Yes |
| SIMV-PC | Yes | | Yes |
| SIMV-VG | Yes | | Yes |
| PS | Yes | | Yes |
| CPAP/PS | Yes | | Yes |
| APRV | Yes | | Yes |
| ***Specifications - Anesthetic Ventilator setting parameter*** | | | |
| Tidal Volume range | 10 to 2000mL (VCV, SIMV-VC) | | 20 to 1500mL |
| | 5 to 2000mL (PCV-VG, SIMV-VG) | | |
| Inspiratory Pressure range | 5 to 90cm$H_2O$ | | 5 to 70cm$H_2O$ |
| Support Pressure range | 0, 3 to 60cm$H_2O$ | | OFF, 3 to 50cm$H_2O$ |
| Apnea Pressure range | 3 to 60cm$H_2O$ | | 3 to 50cm$H_2O$ |
| Plimit range | 5 to 100cm$H_2O$ | | 10 to 100cm$H_2O$ |
| PEEP range | 0 to 50cm$H_2O$ | | OFF, 3 to 30cm$H_2O$ |
| Tslope range | 0.0 to 2.0s | | 0.0 to 2.0s |
| RR range | 4 to 100bpm | | 4 to 100bpm |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Min RR range | 2 to 60bpm | | 2 to 60bpm |
| I:E range | 4:1 to 1:8 | | 4:1 to 1:8 |
| Apnea I:E range | 4:1 to 1:8 | | 4:1 to 1:8 |
| Apnea Tinsp range | 0.2 to 10s | | 0.2 to 10s |
| Tinsp range | 0.2 to 10s | | 0.2 to 10s |
| Tpause range | OFF, 5% to 60% of Tinsp | | OFF, 5% to 60% of Tinsp |
| Trig Window range | 5% to 80% of Texp | | 25% of Texp |
| F-Trig range | 0.2 to 15L/min | | 0.2 to 15L/min |
| P-Trig range | -20 to -1cm$H_2O$ | | - |
| Exp% range | 5% to 80% | | 25% |
| Phigh range | 3 to 90cm$H_2O$ | | 3 to 70cm$H_2O$ |
| Plow range | 0 to 50cm$H_2O$ | | OFF, 3 to 30cm$H_2O$ |
| Thigh range | 0.2 to 10s | | 0.2 to 10s |
| Tlow range | 0.2 to 10s | | 0.2 to 10s |
| Maximum Inspiratory flow | 180L/min | | 180L/min |
| ***Specifications - Anesthetic Ventilator monitoring parameter*** | | | |
| Tidal Volume range | 0 to 3000mL | | 0 to 3000mL |
| Minute Volume range | 0 to 100L/min | | 0 to 100L/min |
| Airway pressure (PEAK, PLAT, MEAN) range | -20 to 120cm$H_2O$ | | -20 to 120cm$H_2O$ |
| PEEP range | 0 to 70cm$H_2O$ | | 0 to 70cm$H_2O$ |
| RR range | 0 to 150bpm | | 0 to 120bpm |
| Spirometry loop | Flow-Volume, Pressure-Volume and Pressure-Flow | | Flow-Volume, Pressure-Volume and Pressure-Flow |
| Type | Multi-step Recruitment and One-step Recruitment | | Preset Procedure and Pressure Adjust |
| Step range | OFF, 1 to 7 | | OFF, 1 to 7 |
| Breaths | 3 to 10 | | 3 to 10 |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Pressure Hold | 20 to 60cm$H_2O$ | | 20 to 60cm$H_2O$ |
| Hold Time | 10 to 40s | | 10 to 40s |
| PEEP on Exit | 0 to 50cm$H_2O$ | | OFF, 3 to 30cm$H_2O$ |
| ***Specifications - Alarm*** | | | |
| High/Low Minute Volume Alarm | Yes | | Yes |
| High/Low Tidal Volume Alarm | Yes | | Yes |
| High/Low RR Alarm | Yes | | Yes |
| High/Low Airway Pressure Alarm | Yes | | Yes |
| Pressure Limiting Alarm | Yes | | Yes |
| Sub Atmospheric Pressure Alarm | Yes | | Yes |
| Continuous Airway Pressure Alarm | Yes | | Yes |
| Apnea Alarm | Yes | | Yes |
| Apnea >2 Minute Alarm | Yes | | Yes |
| Apnea $CO_2$ Alarm | Yes | | Yes |
| High/Low $FiO_2$ Alarm | Yes | | Yes |
| Pipeline supply | 280 to 600kPa (40 to 87PSI) for $O_2$, $N_2O$, Air | | 280 to 600kPa (40 to 87PSI) for $O_2$, $N_2O$, Air |
| Connector type | DISS | | DISS |
| Pressure monitoring range | 0 to 1000kPa (0 to 140PSI) for $O_2$, $N_2O$, Air | | 0 to 1000kPa (0 to 140PSI) for $O_2$, $N_2O$, Air |
| Pressure monitoring accuracy | ±(4% of the full scale reading+8% of the actual reading) | | ±(4% of the full scale reading+8% of the actual reading) |
| Backup Cylinder supply | **6.9 to 20.0MPa (1000 to 2900PSI) for $O_2$, Air**<br>4.2 to 6.0MPa (600 to 870PSI) for $N_2O$ | | **6.9 to 15.5MPa (1000 to 2250PSI) for $O_2$, Air**<br>4.2 to 6MPa (600 to 870PSI) for $N_2O$ |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Connector type | Pin-index of E cylinder | | Pin-index of E cylinder |
| Pressure monitoring range | 0 to 25MPa (0 to 3500PSI) for $O_2$, Air<br>0 to 10MPa (0 to 1400PSI) for $N_2O$ | | 0 to 25MPa (0 to 3500PSI) for $O_2$, Air<br>0 to 10MPa (0 to 1400PSI) for $N_2O$ |
| Pressure monitoring accuracy | ±(4% of the full scale reading+8% of the actual reading) | | ±(4% of the full scale reading+8% of the actual reading) |
| ***Specifications – Fresh Gas*** | | | |
| Electronic Flowmeter - Direct Flow Control Mode | $O_2$ flow range: 0, 0.2 to 15.0L/min<br>$N_2O$ flow range: 0 to 12L/min<br>Air flow range: 0 to 15L/min<br>$O_2$ flow accuracy: ±50ml/min or ±5% of the setting value, whichever is greater<br>Balance gas (Air/$N_2O$) flow accuracy: ±50ml/min or ±5% of the setting value, whichever is greater | | $O_2$ flow range: 0 to 15L/min<br>$N_2O$ flow range: 0 to 12L/min<br>Air flow range: 0 to 15L/min<br>$O_2$ flow accuracy: ±50ml/min or ±5% of setting value, whichever is greater<br>Balance gas (Air/$N_2O$) flow accuracy: ±50ml/min or ±5% of setting value, whichever is greater |
| Electronic Flowmeter - Total Flow Control Mode | Total Flow Control Mode:<br>**Total flow range: 0, 0.2 to 20.0L/min**<br>Total flow accuracy: ±100ml/min or ±5% of the setting value, whichever is greater<br>$O_2$ concentration range:<br>21% to 100% (Balance gas is Air)<br>26% to 100% (Balance gas is $N_2O$)<br>$O_2$ concentration accuracy:<br>Volume fraction of ±5% (Flow <1L/min)<br>±5% of the setting value (Flow ≥1L/min) | | Total Flow Control Mode:<br>**Total flow range: 0, 0.2 to 18L/min**<br>Total flow accuracy: ±100ml/min or ±5% of setting value, whichever is greater<br>$O_2$ concentration range:<br>21% to 100% (The balance gas is Air)<br>26% to 100% (The balance gas is $N_2O$)<br>$O_2$ concentration accuracy:<br>±5% V/V for flows <1L/min<br>±5% of setting for flows ≥1L/min |
| Optimal Flow Indicator (Optimizer) | Optimum fresh gas flow: Green; Insufficient fresh gas flow: Red; Excessive fresh gas flow: Yellow | | Optimum fresh gas flow: Green; Insufficient fresh gas flow: Red; Excessive fresh gas flow: Yellow |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Backup Flowmeter | $O_2$ flow range: 1.0 to 15L/min<br>Air flow range: 0 to 15L/min<br>Accuracy: ±10% of the indicated value (Under the condition of 20℃ and 101.3kPa, for flow between 10% and 100% of full scale) | | $O_2$ flow range: 1.0 to 15L/min<br>Air flow range: 0 to 15L/min<br>Accuracy: ±10% of the indicated value (Under the condition of 20 ℃ and 101.3kPa, for flow between 10% and 100% of full scale) |
| Oxygen flush flow range | 35 to 50L/min | | 35 to 50L/min |
| Auxiliary Flowmeter | Flow range: 0 to 15L/min<br>$O_2$% range: 21% to 100% | | Flow range: 0 to 15L/min<br>$O_2$% range: 21% to 100% |
| HFNC | Flow range: 2 to 60L/min<br>$O_2$% range: 21% to 100% | | - |
| ***Specifications - Anesthetic Breathing System*** | | | |
| $CO_2$ absorbent volume | 1500mL±100mL | | 1500mL±100mL |
| $CO_2$ absorber | Loose fill or Pre-pak canisters | | Loose fill or Pre-pak canisters |
| APL Valve | Adjustable range: Approximately 0 (SP) to **70cm$H_2O$** | | Adjustable range: Approximately 0 (SP) to **75cm$H_2O$** |
| Airway pressure gauge range | Range: -20 to 100cm$H_2O$<br>Accuracy: ±(2% of the full scale reading+4% of the actual reading) | | Range: -20 to 100cm$H_2O$<br>Accuracy: ±(2% of the full scale reading+4% of the reading) |
| Breathing system safety pressure | 110±10cm$H_2O$ | | 110±10cm$H_2O$ |
| Sample Gas Return | Yes | | Yes |
| Heated Breathing Circuit | Yes | | Yes |
| APL Valve Quick Release | Yes | | Yes |
| ***Specifications - AGSS*** | | | |
| Flow sensor | Inspiration/Expiration flow sensor component | | Inspiration/Expiration flow sensor assembly |
| Active Low-flow AGSS | Yes | | Yes |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Extract flow range of Active Low-flow AGSS | 25 to 50L/min | | 25 to 50L/min |
| Passive AGSS | Yes | | Yes |
| Anesthetic Gas Module (AGM) | 2-slot Anesthetic Gas Module with Oxygen | | 2-slot Anesthetic Gas Module with Oxygen |
| Water trap | DRYLINE II Water trap, Adult/pediatric | | DRYLINE II Water trap, Adult/pediatric |
| | DRYLINE II Water trap, Neonate | | DRYLINE II Water trap, Neonate |
| Sampling Line | DRYLINE Gas Sampling Line, Neonate 2.5 m | | DRYLINE Gas Sampling Line, Neonate 2.5 m |
| | DRYLINE Gas Sampling Line, Adult/pediatric 2.5 m | | DRYLINE Gas Sampling Line, Adult/pediatric 2.5 m |
| Airway adapter | Airway adapter (straight) | | Airway adapter (straight) |
| | Airway adapter (elbow) | | Airway adapter (elbow) |
| Type of $O_2$ Sensor | Paramagnetic | | Paramagnetic |
| Warm-up time | 45s to warm-up status<br>10min to ready-to-measure status | | 45s to warm-up status<br>10min to ready-to-measure status |
| Sample flowrate | Neonate water trap: **100, 110, 120ml/min (Optional)**<br>Adult/pediatric water trap: **150, 180, 200ml/min (Optional)** | | Neonate water trap: **70, 90, 120ml/min (Optional)**<br>Adult/pediatric water trap: **120, 150, 200ml/min (Optional)** |
| Measurement range | $CO_2$: 0.0% to 30%<br>$O_2$: 0% to 100%<br>$N_2O$: 0% to 100%<br>HAL: 0.0% to 30%<br>ISO: 0.0% to 30%<br>ENF: 0.0% to 30%<br>SEV: 0.0% to 30%<br>DES: 0.0% to 30%<br>RR: 2 to 100bpm | | $CO_2$: 0% to 30%<br>$O_2$: 0% to 100%<br>$N_2O$: 0% to 100%<br>HAL: 0% to 30%<br>ISO: 0% to 30%<br>ENF: 0% to 30%<br>SEV: 0% to 30%<br>DES: 0% to 30%<br>RR: 2 to 100bpm |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| $CO_2$ accuracy | 0% to 1%: ±0.1%<br>1% to 5%: ±0.2%<br>5% to 7%: ±0.3%<br>7% to 10%: ±0.5%<br>>10%: Unspecified | | 0% to 1%: ±0.1%<br>1% to 5%: ±0.2%<br>5% to 7%: ±0.3%<br>7% to 10%: ±0.5%<br>>10%: Unspecified |
| $O_2$ accuracy | 0% to 25%: ±1%<br>25% to 80%: ±2%<br>80% to 100%: ±3% | | 0% to 25%: ±1%<br>25% to 80%: ±2%<br>80% to 100%: ±3% |
| $N_2O$ accuracy | 0% to 20%: ±2%<br>20% to 100%: ±3% | | 0% to 20%: ±2%<br>20% to 100%: ±3% |
| HAL, ENF, ISO accuracy | 0% to 1%: ±0.15%<br>1% to 5%: ±0.2%<br>>5%: Unspecified | | 0% to 1%: ±0.15%<br>1% to 5%: ±0.2%<br>>5%: Unspecified |
| SEV accuracy | 0% to 1%: ±0.15%<br>1% to 5%: ±0.2%<br>5% to 8%: ±0.4%<br>>8%: Unspecified | | 0% to 1%: ±0.15%<br>1% to 5%: ±0.2%<br>5% to 8%: ±0.4%<br>>8%: Unspecified |
| DES accuracy | 0% to 1%: ±0.15%<br>1% to 5%: ±0.2%<br>5% to 10%: ±0.4%<br>10% to 15%: ±0.6%<br>15% to 18%: ±1%<br>>18%: Unspecified | | 0% to 1%: ±0.15%<br>1% to 5%: ±0.2%<br>5% to 10%: ±0.4%<br>10% to 15%: ±0.6%<br>15% to 18%: ±1%<br>>18%: Unspecified |
| RR accuracy | 2 to 60bpm: ±1bpm<br>61 to 100bpm: ±2bpm | | 2 to 60bpm: ±1bpm<br>61 to 100bpm: ±2bpm |
| ***Specifications - Oxygen Cell*** | | | |
| Oxygen Cell | Galvanic Fuel cell | | Galvanic Fuel cell |
| Measurement range | 18% to 100% | | 18% to 100% |
| Measurement accuracy | ±(volume percent of 2.5%+2.5% of gas level) | | ±(volume fraction of 2.5%+2.5% gas level) |
| ***Specifications - Negative Pressure Suction Device*** | | | |
| Continuous Negative Pressure Suction | Yes | | Yes |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Performance category | Pharyngeal Suction | | Pharyngeal Suction |
| Maximum vacuum | 69 to 72kPa (517.5 to 540mmHg) with external vacuum applied of 72kPa (540mmHg) and 40L/min free flow | | 69 to 72kPa (517.5 to 540mmHg) with external vacuum applied of 72kPa (540mmHg) and 40L/min free flow |
| Maximum flow | 39 to 40L/min with external vacuum applied of 72kPa (540mmHg) and 40L/min free flow | | 39 to 40L/min with external vacuum applied of 72kPa (540mmHg) and 40L/min free flow |
| Minimum flow | 20L/min | | 20L/min |
| Vacuum gauge accuracy | ±5% of full scale | | ±5% of full scale |
| ***Specifications - Agent usage calculation*** | | | |
| Anesthetic agents(AA) | Isoflurane<br>Sevoflurane<br>Desflurane<br>Halothane | Isoflurane<br>Sevoflurane<br>Desflurane | Isoflurane<br>Sevoflurane<br>Desflurane<br>Halothane<br>Enflurane |
| Agent usage speed range | Isoflurane and Halothane: 0 to 250mL/h<br>Sevoflurane: 0 to 450mL/h<br>Desflurane: 0 to 900mL/h | Isoflurane: 0 to 250mL/h<br>Sevoflurane: 0 to 450mL/h<br>Desflurane: 0 to 900mL/h | Enflurane, Isoflurane and Halothane: 0 to 250mL/h<br>Sevoflurane: 0 to 450mL/h<br>Desflurane: 0 to 900mL/h |
| Agent usage speed accuracy | **±2mL/h or ±15% of the actual reading, whichever is greater** | | **±2mL/h or ±25% of the displayed value, whichever is greater** |
| Agent total usage range | 0 to 3000mL | | 0 to 3000mL |
| ***Specifications - Data from the patient monitor to support the optimizer and the agent usage calculation functions*** | | | |
| Agent total usage accuracy | **±2mL or ±15% of the actual reading, whichever is greater** | | **±2mL or ±25% of the displayed value, whichever is greater** |

| Technical Characteristics | Subject device<br>A8 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Subject device<br>A9 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(Subject device) | Primary predicate<br>A7 Anesthesia System<br><br>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>(K171292) |
|---|---|---|---|
| Receive data from the patient monitor to support the optimizer function and the agent usage calculation function | Receive data from the Anesthetic Gas Module plugged into the Passport 12M/17M patient monitor (K190011) to support the optimizer function and the agent usage calculation function | | Receive data from the Anesthetic Gas Module plugged into the Passport 12M/17M patient monitor (K190011) to support the optimizer function and the agent usage calculation function |
| ***Specifications - Internal Battery*** | | | |
| Battery | **Sealed lead acid battery** | | **Li-Ion (sealed) battery** |
| Capacity | **One or two batteries**<br>**16Ah×1 pcs**<br>**16Ah×2 pcs (Optional)** | **Two batteries**<br>**16Ah×2 pcs** | **Two batteries**<br>**4.5Ah×2 pcs** |
| Operating time (Typical) | **≥90min (1 pcs)**<br>**≥180min (2 pcs)** | **≥90min** | **≥90min** |
| Operating time (Maximum) | **≥50min (1 pcs)**<br>**≥100min (2 pcs)** | **≥50min** | **≥60min** |
| ***Specifications - Other*** | | | |
| Auxiliary Worktable | Available | | Available |
| Top shelf | Available | | Available |
| Monitor bracket | Available | | Available |

In conclusion, there are five technological differences between the subject device (A8, A9 Anesthesia System) and the primary predicate A7 Anesthesia System (K171292):

- Change the Vaporizer Type and the addition of Electronic Vaporizers (A9)
- Change certain parameters of the ventilator modes
- Addition of the High Flow Nasal Cannula Oxygen (HFNC)
- Change the Anesthetic Gas Module and Accessories
- Addition of the Sealed Lead Acid Battery

The differences in technological characteristics do not raise new questions of safety and effectiveness.

# 8. PERFORMANCE DATA

To establish the substantial equivalence of the A8, A9 Anesthesia System, Mindray conducted functional and system level testing on the subject device. The testing provided an evaluation of the performance of the device relevant to each of the differences between the subject device and the predicate device. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.

Mindray has conducted testing to ensure the subject device meets relevant consensus standards.

## Biocompatibility Testing

The A8, A9 Anesthesia System were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-18:2005 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds

## Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification of the A8, A9 Anesthesia System was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

## Electromagnetic Compatibility and Electrical Safety

The A8, A9 Anesthesia System were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI 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 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8 Edition 2.1 2012-11 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
- 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 anaesthetic workstation [including: Amendment 1 2015-03-01 and Amendment 2 2018-07]
- ISO 80601-2-55 Second edition 2018-02 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

## Bench Testing

To establish the substantial equivalence of the A8, A9 Anesthesia System, Mindray conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification and is substantially equivalent to the predicate device.

In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.

- ASTM F1101-90 (Reapproved 2003) Standard Specification for Ventilators Intended for Use During Anesthesia
- IEC 60601-1-6 Edition 3.1 2013-10 General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2012 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
- ISO 5360 Fourth edition 2016-02-15 Anaesthetic vaporizers — Agent-specific filling systems
- ISO 10079-3 Third edition 2014-05-01 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source

- ISO 80601-2-13:2011/ Amd.1:2015/Amd.2:2018 Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
- ISO 80601-2-55 Second edition 2018-02 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

## 9. CONCLUSION

Based on the detailed comparison of specifications for each of the characteristics to the predicate devices, the performance testing and conformance with applicable standards, the A8, A9 Anesthesia System can be found substantially equivalent to the predicate devices.