June 25, 2026

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

Re: K253330
Trade/Device Name: A5 Anesthesia System (A5); A7 Anesthesia System (A7)
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, KOI, OLW, OLT, OMC, ORT
Dated: May 22, 2026
Received: May 22, 2026

Dear Li Lei:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253330

Please provide the device trade name(s).

A5 Anesthesia System (A5);
A7 Anesthesia System (A7)

Please provide your Indications for Use below.

The 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 Anesthesia System 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

1. SUBMITTER

Applicant: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: May 22, 2026

2. DEVICE

Device Trade Name: A5, A7 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
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
868.2775, II	KOI	Electrical peripheral nerve stimulator	Stimulator, nerve, peripheral, electric
882.1400, II	OLW	Electroencephalograph.	Index-generating electroencephalograph software

Regulation Number/Class	Product Code	Regulation description	Device Common Name
882.1400, II	OLT	Electroencephalograph	Non-normalizing quantitative electroencephalograph software
882.1400, II	OMC	Electroencephalograph	Reduced- montage standard electroencephalograph
882.1400, II	ORT	Electroencephalograph	Burst suppression detection software for electroencephalograph

3. PREDICATE DEVICE

Primary predicate:

- K201957 – A8 Anesthesia System, ShenZhen Mindray Bio-Medical Electronics Co., Ltd.

4. REFERENCE DEVICES

- K192972 - BeneVision N Series Patient Monitors, ShenZhen Mindray Bio-Medical Electronics Co., LTD.
- K201874 - Maquet Servo-U Ventilator, Maquet Critical Care AB
- K220107 - SV600 Ventilator, ShenZhen Mindray Bio-Medical Electronics Co., Ltd.
- K230931 - Atlan Anesthesia machine, Drägerwerk AG & Co. KGaA
- K121225 - Hamilton-C2 Ventilator, HAMILTON MEDICAL AG
- K171311 - A5 Anesthesia System, ShenZhen Mindray Bio-Medical Electronics Co., Ltd.
- K230693 - BIS™ Advance Monitoring System, Covidien LLC.

5. DEVICE DESCRIPTION

The A5, 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 A5, A7 Anesthesia System incorporates O_2, CO_2, N_2O and Agent concentration monitoring (Desflurane, Isoflurane, Halothane, Enflurane and Sevoflurane). The A5, A7 Anesthesia System of this 510(k) is a modified version of the previously cleared A8 Anesthesia System (K201957).

6. INTENDED USE/INDICATIONS FOR USE

The A5, 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 A5, A7 Anesthesia System 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

The primary predicate A8 Anesthesia System (K201957) and the subject device A5, A7 Anesthesia System Indications for Use are the same. 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 A5, A7 Anesthesia System were cleared in the primary predicate A8 Anesthesia System (K201957).

Comparison of Technological Characteristics

Table 2 compares the key technological features of the subject devices to the primary predicate device (A8 Anesthesia System (K201957)) and reference device.

Table 2: Technological Characteristics Comparison

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
Anesthetic ventilator				
Working Mode	Standby mode		Standby mode	-
	Manual Ventilation mode		Manual Ventilation mode	-
	Automatic Ventilator mode		Automatic Ventilator mode	-
	Lung Recruitment Ventilation		Lung Recruitment Ventilation	-
	Cardiac Bypass mode		Cardiac Bypass mode	-
	ACGO mode		ACGO mode	-
	Flow Pause		Flow Pause	-
	Monitor mode		Monitor mode	-
Automatic	VCV		VCV	-

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
Ventilation mode	PCV		PCV	-
	PCV-VG		PCV-VG	-
	SIMV-VC		SIMV-VC	-
	SIMV-PC		SIMV-PC	-
	SIMV-VG		SIMV-VG	-
	PS		PS	-
	CPAP/PS		CPAP/PS	-
	APRV		APRV	-
	AMV		-	SV600 Ventilator (K220107)
Anesthetic Ventilator setting parameter	Tidal Volume, Inspiratory Pressure, Support Pressure, Apnea Pressure, Plimit, PEEP, Tslope, RR, Min RR, I:E ,Apnea I:E ,Apnea Tinsp, Tinsp, Tpause, Trig Window, F-Trig, P-Trig, Exp%, Phigh, Plow, Thigh, Tlow, MV%		Tidal Volume, Inspiratory Pressure, Support Pressure, Apnea Pressure, Plimit, PEEP, Tslope, RR, Min RR, I:E, Apnea I:E, Apnea Tinsp, Tinsp,Tpause, Trig Window, F-Trig, P-Trig, Exp%, Phigh, Plow , Thigh, Tlow ,	-
Anesthetic Ventilator monitoring parameter	Tidal Volume, Minute Volume (MV, MVmand , MVspon), Airway pressure, PEEP, Respiratory Rate (RR, RRmand, RRspon), I:E, Resistance (Raw) , Compliance (Compl) , Minute Volume leakage (MVLeak) , Inspiratory-Expiratory Tidal volume difference △Vt, Drive pressure range, Time Constant (TC)		Tidal Volume, Minute Volume, Airway pressure, PEEP, Respiratory Rate, I:E, Resistance (Raw) , Compliance (Compl) , Minute Volume leakage (MVLeak)	-
	Elastance (E)		-	Servo-U (K201874)
	Mechanical Power, Work of breathing (WOBtot, WOBvent, WOBpat)		-	SV600 Ventilator (K220107)
Gas Advanced Monitoring Values	AA Uptake, O2 Uptake, MVxCO2		-	Altan (K230931)
Inspiration hold	Yes		-	SV600 Ventilator (K220107)
Expiration hold	Yes		-	
IntelliCycle	Yes		-	SV600 Ventilator (K220107)
Spirometry loop	Flow-Volume, Pressure-Volume and Pressure-Flow		Flow-Volume, Pressure-Volume and Pressure-Flow	-

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
Maximum Inspiratory flow	180L/min		180L/min	-
Lung Recruitment Ventilation	Multi-step Recruitment and One-step Recruitment		Multi-step Recruitment and One-step Recruitment	-
Basic Alarm	High/Low Minute Volume Alarm High/Low Tidal Volume Alarm High/Low RR Alarm High/Low Airway Pressure Alarm Pressure Limiting Alarm Sub Atmospheric Pressure Alarm Continuous Airway Pressure Alarm Apnea Alarm Apnea >2 Minute Alarm Apnea CO2 Alarm High/Low FiO2 Alarm		High/Low Minute Volume Alarm High/Low Tidal Volume Alarm High/Low RR Alarm High/Low Airway Pressure Alarm Pressure Limiting Alarm Sub Atmospheric Pressure Alarm Continuous Airway Pressure Alarm Apnea Alarm Apnea >2 Minute Alarm Apnea CO2 Alarm High/Low FiO2 Alarm	-
Gas supply				
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;	-
Backup Cylinder supply	6.9 to 20.0MPa (1000 to 2900PSI) for O_2, Air 4.2 to 6.0MPa (600 to 870PSI) for N_2O		6.9 to 20.0MPa (1000 to 2900PSI) for O_2, Air 4.2 to 6.0MPa (600 to 870PSI) for N_2O	-
Fresh Gas				
Electronic Flowmeter	-	**Direct Flow Control Mode:** O_2 flow range: 0, 0.2 to 15L/min N_2O flow range: 0 to 12L/min Air flow range: 0 to 15L/min O_2 concentration range in the O_2/N_2O mixed gas: ≥25%	**Direct Flow Control Mode:** O_2 flow range: 0, 0.2 to 15.0L/min N_2O flow range: 0 to 12L/min Air flow range: 0 to 15L/min O_2 concentration range in the O_2/N_2O mixed gas: ≥25%	-

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
	-	**Total Flow Control Mode:** Total flow range: 0, 0.2 to 20L/min O_2 concentration range: 21% to 100% (Balance gas is Air) 26% to 100 (Balance gas is N_2O)	**Total Flow Control Mode:** Total flow range: 0, 0.2 to 20.0L/min O_2 concentration range: 21% to 100% (Balance gas is Air) 26% to 100% (Balance gas is N_2O)	-
Backup Flowmeter	-	Yes	Yes	-
Flowmeter	O_2 flow range: 0 to 15.0L/min N_2O flow range: 0 to 12.0L/min Air flow range: 0 to 15.0L/min O_2 concentration range in the O2/N2O mixed gas: ≥25%	-	O_2 flow range: 0, 0.2 to 15.0L/min N_2O flow range: 0 to 12L/min Air flow range: 0 to 15L/min O_2 concentration range in the O2/N2O mixed gas: ≥25%	-
Optimal Flow Indicator (Optimizer)	Yes		Yes	-
Oxygen flush	Yes		Yes	-
Auxiliary Gas				
Auxiliary Flowmeter	Flow range: 0 to 15L/min O_2% range: 21% to 100%		Flow range: 0 to 15L/min O_2% range: 21% to 100%	-
HFNC	Flow range: 2 to 60L/min O_2% range: 21% to 100%		Flow range: 2 to 60L/min O_2% range: 21% to 100%	-
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 70cmH_2O		Adjustable range: Approximately 0 (SP) to 70cmH_2O	-
APL Valve Quick Release	Yes		Yes	-

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
Airway pressure gauge range	-20 to 100cmH_2O		-20 to 100cmH_2O	-
Breathing system safety pressure	110±10cmH_2O		110±10cmH_2O	-
Sample Gas Return	Yes		Yes	-
Heated Breathing Circuit	Yes		Yes	-
AGSS				
Active Low-flow AGSS	Yes		Yes	-
Extract flow range of Active Low-flow AGSS	25 to 50L/min		25 to 50L/min	-
Passive AGSS	Yes		Yes	-
Anesthetic Gas Module (AGM)				
Sample flowrate	Neonate water trap: 100, 110, 120ml/min (Optional) Adult/pediatric water trap: 150, 180, 200ml/min (Optional)		Neonate water trap: 100, 110, 120ml/min (Optional) Adult/pediatric water trap: 150, 180, 200ml/min (Optional)	-
Measurement range	CO_2: 0.0% to 30% O_2: 0% to 100% N_2O: 0% to 100% HAL: 0.0% to 30% ISO: 0.0% to 30% ENF: 0.0% to 30% SEV: 0.0% to 30% DES: 0.0% to 30% RR: 2 to 100bpm		CO_2: 0% to 30% O_2: 0% to 100% N_2O: 0% to 100% HAL: 0% to 30% ISO: 0% to 30% ENF: 0% to 30% SEV: 0% to 30% DES: 0% to 30% RR: 2 to 100bpm	-
Oxygen Cell				
Measurement range	18% to 100%		18% to 100%	-
BIS Module				
Measured parameters	EEG BIS, BIS L, BIS R: 0 to 100		-	BeneVision N Series Patient Monitors

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
Calculated parameters	SQI, SQI L, SQI R: 0% to 100% EMG, EMG L, EMG R: 0dB to 100dB SR, SR L, SR R: 0% to 100% SEF, SEF L, SEF R: 0.5Hz to 30.0 Hz TP, TP L, TP R: 40dB to 100dB BC, BC L, BC R: 0 to 30 sBIS L, sBIS R: 0 to 10.0 sEMG L, sEMG R: 0 to 10.0 ASYM: 0% to 100%		-	(K192972)
NMT Module				
TOF (Train Of Four) mode	TOF-Ratio (Response percentage): 5% to 160% TOF-Count (Number of responses): 0 to 4 TOF-T1% (Response to the first stimulus as percentage of the reference value): 0% to 200%		-	BeneVision N Series Patient Monitors (K192972)
ST (Single Twitch) mode	ST-Ratio (Response percentage): 0% to 200%		-	
DBS (Double-Burst Stimulation) 3.2/3.3 mode	DBS-Ratio (Response percentage): 5% to 160% DBS-Count (Number of responses): 0 to 2		-	
PTC (Post-Tetanic Count) mode	PTC-Count (Number of responses): 0 to 20		-	
Agent usage calculation				
Agent usage calculation	Agent usage speed range: Isoflurane: 0 to 250mL/h Sevoflurane: 0 to 450mL/h Desflurane: 0 to 900mL/h Agent total usage range: 0 to 3000mL		Agent usage speed range: Isoflurane and Halothane: 0 to 250mL/h Sevoflurane: 0 to 450mL/h Desflurane: 0 to 900mL/h Agent total usage range: 0 to 3000mL	-
Others				
Folding Auxiliary Worktable	Yes		Yes	-
Top shelf	Yes		Yes	-
Mounting Bracket	Yes		Yes	-

Technical Characteristics	Subject device A5 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Subject device A7 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate A8 Anesthesia System Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K201957)	Reference Device(s)
Through RJ45 network port to send data to other device	Yes		Yes	-

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

8. PERFORMANCE DATA

To establish the substantial equivalence of the A5, A7 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 A5, A7 Anesthesia System was 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 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-18:2020, Amd 2022, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)
- ISO 18562-1:2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

- ISO 18562-3:2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4:2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance " Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff". Verification of the A5, A7 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 A5, A7 Anesthesia System were assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1:2020, Ed. 3.2, CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2:2020 Ed. 4.1 CONSOLIDATED VERSION, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests
- ISO 80601-2-13:2011, Ed. 1, Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]
- ISO 80601-2-55:2018, Ed. 2, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC TR 60601-4-2:2016, Ed. 1, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Bench Testing

To establish the substantial equivalence of the A5, A7 Anesthesia System, Mindray conducted functional and system level testing on the device. 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.

- IEC 60601-1-6 :2020, Ed. 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2020 Ed. 2.2, 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 80601-2-13:2011, Ed. 1, Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]
- ISO 80601-2-55:2018, Ed. 2, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 5356-1:2015, Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
- IEC 60601-2-10:2016, Ed. 2.1, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 80601-2-26:2019, Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

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 A5, A7 Anesthesia System can be found substantially equivalent to the predicate devices.