October 24, 2018

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South High-tech Industrial
Park, Nanshan
Shenzhen, 518057 CN

Re: K180788
Trade/Device Name: Gas Module 3
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: Class II
Product Code: BZK
Dated: September 19, 2018
Received: September 24, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180788

Device Name
Gas Module 3

Indications for Use *(Describe)*
The indications for use for the Gas Module 3 include monitoring of airway gases during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and post anesthesia care units (PACU), etc.

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 Gas Module 3 is provided below.

Device Common Name: Spirometer, Monitoring (W/wo Alarm)

Device Proprietary Name: Gas Module 3

Submitter:

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Date Prepared: October 23, 2018

Classification Regulation: 21 CFR 868.1850, Class II, Monitoring spirometer

Panel: Anesthesiology

Classification Regulation, Classification Name and Product Codes:

Primary				
Product Code	**Regulation Number**	**Panel**	**Regulation description**	**Device Common Name**
BZK	21 CFR 868.1850	Anesthesiology	Monitoring spirometer	Spirometer, Monitoring (W/wo Alarm)

Primary Predicate Device: K062754 - GAS MODULE SE; DATASCOPE CORP.

Indications for Use:

The indications for use for the Gas Module 3 include monitoring of airway gases during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and post anesthesia care units (PACU), etc.

Device Description:

The Gas Module 3 is an independently powered unit capable of interfacing with Mindray DS USA, Inc. (hereafter MRDS) Patient Monitors using a proprietary communications protocol. The system connects to the patient monitor via a RS232 connector. All Gas Module 3 data display on the monitor screen. And all user commands are entered on the monitor and then electronically transmitted to the Gas Module 3.

The Gas Module 3 measures in real-time, breath-by-breath CO_2, O_2, N_2O gases. Additionally, the Gas Module 3 monitors the anesthetic agents Halothane (HAL), Isoflurane (ISO), Sevoflurane (SEV), Desflurane (DES) and Enflurane (ENF).

The Gas Module 3 consists of AION Multigas Analyzer, Servomex Paramagnetic Oxygen sensor, Power supply Board and Communication Board.

The subject device is a modified version of a previously cleared model, the Gas Module SE. The Gas Module SE was cleared under K062754, on September 13, 2006.

Non-clinical testing:

EMC and Electrical Safety - To establish the substantial equivalence of the subject Gas Module 3 to the previously cleared Gas Module SE (K062754), Mindray conducted additional Electromagnetic Compatibility and Electrical Safety testing level testing on the subject device. The testing provides an evaluation of the EMC and electrical safety of the subject devices relevant to each of the modifications since clearance of the predicate Gas Module SE. The Electromagnetic Compatibility and Electrical Safety testing shows that the subject device continues to meet the specifications and the performance of the subject device is equivalent to the predicate device.

- AAMI ANSI ES 60601-1: 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and

A2:2010/(R)2012* Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Performance Testing – Bench - To establish the substantial equivalence of the subject Gas Module 3 to the previously cleared Gas Module SE (K062754), Mindray conducted functional and system level testing on the subject devices. The testing provides an evaluation of the performance of the subject devices relevant to each of the modifications since clearance of the Gas Module SE. The functional and system level testing shows that the subject device continues to meet the specifications and the performance of the subject device is equivalent to the predicate device.

In addition, Mindray has conducted testing to ensure the subject device meets following consensus standards.

- ISO 80601-2-55: 2011 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors

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 subject Gas Module 3 was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Substantial Equivalence:

Comparison of Indications - The indication for use of the subject device (Gas Module 3) is identical to that of the predicate device (Gas Module SE), with only the device name changed. The minor change to the indication for use does not change the fundamental intended use of the Gas Module 3.

Comparison of Technological Characteristics - The table below compares the key technological feature of the subject device to the primary predicate device (Gas Module SE, K062754). The features in gray are the main features that have been modified since their previous clearances.

Device Comparison Table

Feature	Predicate Device (K062754)	Subject Device	Comparison analysis
	Gas Module SE	Gas Module 3	
Indications for Use	The indications for use for the Gas Module SE include monitoring of airway gases, during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and post anesthesia care units (PACU), etc.	The indications for use for the Gas Module 3 include monitoring of airway gases during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and post anesthesia care units (PACU), etc.	Same The indication for use of the subject device (Gas Module 3) is identical to that of the predicate device (Gas Module SE), with only the device name changed.
Power supply	Multi-voltage power supply, source 100-240VAC, 50-60Hz.	Multi-voltage power supply, source 100-240VAC, 50-60Hz.	Same
User interface	Operation is controlled by a connected patient monitor via Mindray DS USA proprietary communication protocol by a RS232 connector.	Operation is controlled by a connected patient monitor via Mindray DS USA proprietary communication protocol by a RS232 connector.	Same
Measured gases	CO_2, O_2, N_2O and Anesthetic agents (Halothane, Isoflurane, Sevoflurane, Desflurane and Enflurane).	CO_2, O_2, N_2O and Anesthetic agents (Halothane, Isoflurane, Sevoflurane, Desflurane and Enflurane).	Same
Measured parameters	Patient inspired/expired gas concentration and respiration rate.	Patient inspired/expired gas concentration and respiration rate.	Same

Warm-up time	2 minutes to operation with CO_2, O_2 and N_2O. 5 minutes to operation of anesthetic agents. 30 minutes for full specification.	45 seconds to operation with CO_2, O_2, N_2O and anesthetic agents. 10 minutes for full specification.	Similar, warm-up time improved in Gas Module 3.
Sampling rate	The sampling system takes care of drawing a gas sample to analyzers at a fixed rate (200±20ml/min).	200±20ml/min with larger size water trap. 120±12ml/min with smaller sizewater trap.	Same - The flow rate for larger size water trap is the same. The option to use a new smaller size water trap is introduced which support a flow rate of 120ml/min, which may provide enhanced gas management for smaller sized patients.
Gas sampling accessories	Water trap	Adult/Pediatric Water trap Neonate Water trap	The water trap and sampling line is changed from Datex-Ohmeda to Artema Technology.
	Sampling line	Adult/Pediatric Sampling line Neonate Sampling line	

	Adapter, Straight Adapter, Elbow	Adapter, Straight Adapter, Elbow	In Gas Module SE, there is one water trap (PN: 0202-00-0129) and one sample line (PN: 0683-00-0451-10) for all patient types (Adult, Pediatric and Neonate) with the sample line flow rate setting 200ml/min. In Gas Module 3, there is one water trap (PN: 0202-00-0182-10) and sample line (PN: 0683-00-0525-25) for adult and pediatric patient with the sampling flow rate setting 200ml/min. And a small size water trap (PN: 0202-00-0181-10) and sample line (PN: 0683-00-0524-25) is introduced for the flow rate 120ml/min, which is an enhancement for neonate patients. The adapter is the same.

Measurement range	CO_2: 0 to 15% O_2: 0 to 100% N_2O: 0 to 100% DES: 0 to 20% SEV: 0 to 8% ENF: 0 to 6% ISO: 0 to 6% HAL: 0 to 6% awRR: 4 to 60 rpm	CO_2: 0 to 10% O_2: 0 to 100% N_2O: 0 to 100% DES: 0 to 18% SEV: 0 to 8% ENF: 0 to 5% ISO: 0 to 5% HAL: 0 to 5% awRR: 2 to 100 rpm	Although the measurement range of CO_2, DES, ENF, ISO and HAL for subject device is small than the predicate device, the difference in the measurement range of these gases for the subject device is insignificant in for the clinical use. The awRR measurement range for the subject device is wider than the predicate device. The awRR measurement range of the subject device has been tested using the test apparatus in figure 201.101 of ISO80601-2-55, and the test result meets the specification.
Full accuracy	CO_2 accuracy: ±(0.2% + 2% of reading)	CO_2 accuracy: ±0.1% @ 0 – 1% ±0.2% @ 1 – 5% ±0.3% @ 5 – 7% ±0.5% @ 7 – 10% Unspecified @ > 10%	The CO_2 measurement accuracy is now specified in different ranges. These accuracies in different ranges meet the requirements of ISO 80601-2-55.
	O_2 accuracy: ±(1% + 2% of reading)	O_2 accuracy: ±1% @ 0 – 25% ±2% @ 25 – 80% ±3% @ 80 – 100%	The O_2 measurement accuracy is now specified in different ranges. These accuracies in different ranges continue to meet the requirements of ISO 80601-2-55.

	N_2O accuracy: ±(1% + 2% of reading)	N_2O accuracy: ±2% @ 0 – 20% ±3% @ 20 – 100%	The N_2O measurement accuracy is now specified in different ranges. These accuracies in different ranges continue to meet the requirements of ISO 80601-2-55.
	DES accuracy: ±(0.15% + 5% of reading)	DES accuracy: ± 0.1 % @ 0 - 1% ± 0.2 % @ 1 - 5% ± 0.4 % @ 5 - 10% ±0.6 % @ 10 - 15% ±1 % @ 15 - 18% Unspecified @ > 18%	The DES measurement accuracy is now specified in different ranges. These accuracies in different ranges still meet the requirements of ISO 80601-2-55.
	SEV accuracy: ±(0.15% + 5% of reading)	SEV accuracy: ±0.15 % @ 0 - 1% ± 0.2 % @ 1 - 5% ±0.4 % @ 5 - 8% Unspecified @ > 8%	The SEV measurement accuracy is now specified in different ranges. These accuracies in different ranges continue to meet the requirements of ISO 80601-2-55.
	ENF accuracy: ±(0.15% + 5% of reading)	ENF accuracy: ±0.15 % @ 0 - 1% ± 0.2 % @ 1 - 5% Unspecified @ > 5%	The ENF measurement accuracy is now specified in different ranges. These accuracies in different ranges continue to meet the requirements of ISO 80601-2-55.
	ISO accuracy: ±(0.15% + 5% of reading)	ISO accuracy: ±0.15 % @ 0 - 1% ± 0.2 % @ 1 - 5% Unspecified @ > 5%	The ISO measurement accuracy is now specified in different ranges. These accuracies in different ranges continue to meet the requirements of ISO 80601-2-55.

	HAL accuracy: ±(0.15% + 5% of reading)	HAL accuracy: ±0.15 % @ 0 - 1% ± 0.2 % @ 1 - 5% Unspecified @ > 5%	The Hal measurement accuracy is now specified in different ranges. These accuracies in different ranges continue to meet the requirements of ISO 80601-2-55.
Rise time	CO_2 rise time: < 400ms	CO_2 rise time: < 250 ms for 200ml/min CO_2 rise time: < 250 ms for 120ml/min	The CO_2 rise time for subject device is smaller than the predicate device. The smaller rise time means the device can detect the variety of the concentration of the gas with greater sensitively.
	O_2 rise time : < 400ms	O_2 rise time: < 400 ms for 200ml/min O_2 rise time: < 450 ms for 120ml/min	The difference of rise time between the subject device and the predicate device is insignificant in clinical use. So no clinical risks or safety issue introduced.
	N_2O rise time: < 400ms	N_2O rise time: < 250 ms for 200ml/min N_2O rise time: < 250 ms for 120ml/min	The N_2O rise time for subject device is smaller than the predicate device.
	DES rise time: <600ms	DES rise time: <300ms for 200ml/min. DES rise time: <300ms for 120ml/min.	The DES rise time for subject device is smaller than the predicate device.
	SEV rise time: <600ms	SEV rise time: <300ms for 200ml/min. SEV rise time: <300ms for 120ml/min.	The SEV rise time for subject device is smaller than the predicate device.
	ENF rise time: <600ms	ENF rise time: <350ms for 200ml/min. ENF rise time: <350ms for 120ml/min.	The ENF rise time for subject device is smaller than the predicate device.

	ISO rise time: <600ms	ISO rise time: <300ms for 200ml/min. ISO rise time: <300ms for 120ml/min.	The ISO rise time for subject device is smaller than the predicate device.
	HAL rise time: <1000ms	HAL rise time: <300ms for 200ml/min. HAL rise time: <300ms for 120ml/min.	The HAL rise time for subject device is smaller than the predicate device.
Delay time	All gases delay time: <2.5 s	All gases delay time: <4 s for 200ml/min All gases delay time: <4 s for 120ml/min	The difference of delay time between the subject device and the predicate device is insignificant in clinical use. So no clinical risks or safety issue introduced.

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications and modifications to the subject device (Gas Module 3), predicted device (Gas Module SE, K062754), the performance testing results and conformance with applicable standards the Gas Module 3 can be found substantially equivalent to the predicate device.