April 6, 2026

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Lei Li
Manager Regulatory Affairs
Mindray Bldg., Keji 12th Rd. S.
Hi-Tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
China

Re: K252182
Trade/Device Name: SV70 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNT
Dated: March 6, 2026
Received: March 6, 2026

Dear Lei Li:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K252182

Device Name
SV70 Ventilator

Indications for Use *(Describe)*

The SV70 Ventilator is intended for use in a professional healthcare facility or during transport in a professional healthcare facility.

The SV70 Ventilator is intended to provide ventilation assistance and breathing support for adult and pediatric patients with a minimum body weight of 20 kg, who are spontaneously breathing individuals with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea.

The SV70 Ventilator should be operated by properly-trained and authorized medical personnel. This equipment is not suitable for use in an MRI environment.

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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1. SUBMITTER

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Date prepared: April 2, 2026

2. DEVICE

Device Name:	SV70 Ventilator
Common Name:	Continuous ventilator
Classification Name:	21 CFR 868.5895, Class II, Continuous ventilator
Product Code:	MNT
Panel:	Anesthesiology

3. PREDICATE DEVICES

Primary Predicate Device:

K082660, V60 Ventilator, Respironics Inc

Secondary Predicate Device:

K213521, NKV-330 Ventilator, Nihon Kohden OrangeMed, Inc

- Supports Ventilation Mode: S mode, O2 Therapy mode.
- Supports Setting Parameters: O2 Therapy Flow.
- Supports Monitoring Parameters: Ppeak, PEEP/PEEPtotal, FiO2, ftotal/fspn, PEF, Flow range.

Reference Devices

K220107, Mindray SV600, SV800 Ventilator, ShenZhen Mindray Bio-Medical Electronics CO., LTD.

- Supports Monitoring Parameters: Ppeak, PEEP/PEEPtotal, FiO2, ftotal/fspn, PEF, PEEPi, PesI/PesE, ΔPes, PtpI/PtpE/ΔPtp.

K193228 - Hamilton-G5 Ventilator, Hamilton Medical AG

- Supports Monitoring Parameters: PTPes, PTPes/min.

K213799, 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 sidestream and microstream CO2 measurement.
- Supports Mindray, Masimo and Nellcor SpO2 measurement

4. DEVICE DESCRIPTION

The SV70Ventilator are turbine blower-driven and electronically-controlled Ventilator. The Ventilator consists of a main unit (including pneumatic circuit, electronic system, mechanical structure, display, CO2 module, SpO2 module), trolley and support arm. The device is equipped with various alarms and safety functions for the modes listed in Table 1 below. The SV70 includes the following features:

- EasySync™ trigger mechanism
- RAMP functionality
- SpO_2 monitoring capability
- CO_2 monitoring capability
- Auxiliary pressure monitoring capability
- O_2 Therapy

5. INDICATIONS FOR USE

The SV70 Ventilator is intended for use in a professional healthcare facility or during transport in a professional healthcare facility.

The SV70 Ventilator is intended to provide ventilation assistance and breathing support for adult and pediatric patients with a minimum body weight of 20 kg, who are spontaneously breathing individuals with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea.

The SV70 Ventilator should be operated by properly-trained and authorized medical personnel. This equipment is not suitable for use in an MRI environment.

6. SUBSTANTIAL EQUIVALENCE

Table 1 below compares technology characteristics and performance specifications.

Table 1: Technological Comparison to Predicate Devices

Technical Characteristics	**Subject device** **SV70 Ventilator** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**	**Primary predicate** **V60 Ventilator** **Respironics Inc.** **(K082660)**	**Comments**
Indication for Use	The SV70 Ventilator is intended for use in a professional healthcare facility or during transport in a professional healthcare facility. The SV70 Ventilator is intended to provide ventilation assistance and breathing support for adult and pediatric patients with a minimum body weight of 20 kg, who are spontaneously breathing individuals with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea. The SV70 Ventilator should be operated by properly-trained and authorized medical personnel. This equipment is not suitable for use in an MRI environment.	The Respironics V60/V60 Plus Ventilator is an assist ventilator and is intended to augment patient breathing. It is intended for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician. The ventilator is intended to support pediatric patients weighing 20 kg (44 lb) or greater to adult patients. It is also intended for intubated patients meeting the same selection criteria as the noninvasive applications. The ventilator is intended to be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists. The ventilator is intended to be used only with various combinations of Respironics-recommended patient circuits, interfaces (masks), humidifiers, and other accessories.	The indications and patient population are same as V60
Ventilation mode			
CPAP	Yes	CPAP	Same
S	Yes	S/T	Same as the S function of V60's S/T mode, S/T mode contains S mode. Compared to V60 and NKV-330 for comparison supplement.
S/T	Yes	S/T	Same
P-A/C	Yes	PCV	Different name, same function.
VAPS	Yes	AVAPS	Different name, same function.

Technical Characteristics	**Subject device** **SV70 Ventilator** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**	**Primary predicate** **V60 Ventilator** **Respironics Inc.** **(K082660)**	**Comments**
PPV	Yes	PPV	Same
O2 Therapy	Yes	-	Compared to NKV330 for comparison supplement
Apnea Ventilation	Yes	Yes	Same
Specifications			
Ventilator setting parameter	Yes	Yes	Same
Ventilator monitoring parameter	Yes	Yes	Some parameters are the same as the V60, other parameters are the same as the NKV-330 or SV600, SV800.
O2 Therapy	Yes	-	Compared to NKV-330 for comparison supplement.
Pressure Relief	Yes	Yes	Same
Ramp	Yes	Yes	Same
EasySync	Yes	Yes	Similar
Auxiliary Pressure	Yes	-	Same as the SV600, SV800.
O2↑(Oxygen Enrichment)	Yes	Yes	Same
Backup Ventilation	Yes	Yes	Same
Leakage Compensation	Yes	Yes	Same
Sidestream CO2	Yes	-	Same as the BeneVision N Series Patient Monitors.
Microstream CO2	Yes	-	Same as the BeneVision N Series Patient Monitors.
Mindray SpO2	Yes	-	Same as the BeneVision N Series Patient Monitors.

Technical Characteristics	Subject device SV70 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Primary predicate V60 Ventilator Respironics Inc. (K082660)	Comments
Masimo SpO2	Yes	-	Same as the BeneVision N Series Patient Monitors.
Nellcor SpO2	Yes	-	Same as the BeneVision N Series Patient Monitors.
"-" means not applicable.			

7. PERFORMANCE DATA

To establish the substantial equivalence of the SV70 Ventilators, 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. Mindray also conducted human factors testing to demonstrate that the device is safe and effective for the intended users, uses and use environments.

Biocompatibility Testing

The SV70 Ventilators was assessed for conformity with the relevant requirements of the following standards and found to comply:

- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 18562-1 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3 First edition 2017-03 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 SV70 Ventilators was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Electromagnetic Compatibility (EMC) and Electrical Safety

The SV70 Ventilators were assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1 Edition 3.2 2020-08 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 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEEE ANSI USEMCSC C63.27-2021American National Standard for Evaluation of Wireless Coexistence
- IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8 Edition 2.2 2020-07 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 80601-2-12 Second edition 2020-02 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- 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
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

- ISO 80601-2-90 First edition 2021 Medical electrical equipment —Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

Bench Testing

To establish the substantial equivalence of the SV70 Ventilators, 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.

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8 Edition 2.2 2020-07 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 80601-2-12 Second edition 2020-02 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- 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
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ASTM F1100-90 (Reapproved 1997) Standard Specification for Ventilator Intended for Use in Critical Care (only Endurance Testing)
- ISO 80601-2-90 First edition 2021 Medical electrical equipment —Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

8. 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 SV70 Ventilator can be found substantially equivalent to the predicate devices. The subject device contains the same ventilation mode parameters as the primary or secondary predicate, with specification ranges for these parameters being equivalent. The intended use of the SV70 Ventilator is the same as the primary predicate. Finally, performance testing, including biocompatibility, EMC, electrical safety, software V&V, and bench testing per FDA-recognized

standards, demonstrates that the SV70 is substantially equivalent to predicates.