August 28, 2025

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

Re: K243767
Trade/Device Name: SV600, SV800 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: August 1, 2025
Received: August 1, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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, Respiratory Devices Team
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243767

Device Name
SV600, SV800 Ventilator

Indications for Use *(Describe)*
The SV600, SV800 Ventilator is intended to be used in intensive care situations for long-term or during transport within a professional healthcare facility. The SV600, SV800 Ventilator is intended to provide ventilation assistance and breathing support for adult, pediatric and neonate patients with a minimum body weight of 0.5 kg. The SV600, SV800 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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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mindray SV600, SV800 Ventilator is provided below.

1. SUBMITTER

Applicant: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: December 3, 2024

2. DEVICE

Trade/Device Name: SV600, SV800 Ventilator
Common Name: Continuous Ventilator
Regulation Number: 21 CFR 868.5895
Device Class: Class II
Review Panel: Anesthesiology

3. PREDICATE DEVICES

Primary predicate:

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

Secondary predicate:

- 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.
- K083050 - Evita XL Ventilator, Drager Medical AG & Co. KG
- K180098 - Servo-U Ventilator, Maquet Critical Care AB

4. DEVICE DESCRIPTION

The SV600 and SV800 Ventilators are pneumatically-driven and electronically-controlled ventilators. The Ventilators consists of a main unit (including pneumatic circuit, electronic system, mechanical structure, display, CO_2 module, SpO_2 module), trolley and support arm. The device also includes a neonatal flow sensor and neonatal flow sensor cable, which are used to measure the patient inspiration/expiration flow in neonatal ventilation modes.

5. INTENDED USE/INDICATIONS FOR USE

The SV600, SV800 Ventilator is intended to be used in intensive care situations for long-term or during transport within a professional healthcare facility. The SV600, SV800 Ventilator is intended to provide ventilation assistance and breathing support for adult, pediatric and neonate patients with a minimum body weight of 0.5 kg. The SV600, SV800 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

Comparison of Indications

Comparing with the primary predicate SV600, SV800 Ventilator(K220107) and Secondary predicate Evita XL Ventilator (K083050) and Servo-U Ventilator (K180098), the indications for use for the subject device SV600, SV800 Ventilators are equivalent.

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 K213799 are incorporated into thoes ventilators with no changes to the modules. This predicate supports the CO_2 module and accessories, the SpO_2 module and accessories, WiFi 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 ventilators.

As a conclusion, the indications for use of the subject device SV600, SV800 Ventilators is the same as the primary predicate SV600, SV800 Ventilator as cleared in K220107, secondary predicate Evita XL Ventilator as cleared in K083050, Servo-U Ventilator as cleared in K180098 and the BeneVision N Series Patient Monitors as cleared in K213799.

Comparison of Technological Characteristics

The table below compares the key technological features of the subject devices to the primary predicate device (SV600, SV800 Ventilator (K220107)) and secondary predicate devices. The

main differences between the subject device and the primary predicate SV600, SV800 Ventilators are:

1. A neonatal ventilation option has been added including the ventilation mode nCPAP which is specific only to the neonate population.
2. Modifications of certain parameters to support neonates
3. Addition of a neonatal flow sensor.
4. Addition of oxygen therapy.
5. Addition of a backup air supply (blower) (optional).
6. Addition of WiFi communication.
7. Addition of neonate CO2 measurement.
8. Addition of neonate Mindray SpO2 measurement.
9. Addition of Masimo SpO2 and Nellcor SpO2 measurement.
10. Modification of the main control board.
11. Modification of the display.
12. Modification of the structure of the expiratory valve assembly.

Technical Characteristics	**Subject device** **SV600, SV800 Ventilator** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(Subject device)**	**Primary predicate** **SV600, SV800 Ventilator** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(K220107)**	**Comments**
Ventilation mode			
V-A/C	Yes	V-A/C	Same
P-A/C	Yes	P-A/C	Same
PRVC	Yes	PRVC	Same
V-SIMV	Yes	V-SIMV	Same
P-SIMV	Yes	P-SIMV	Same
PRVC-SIMV	Yes	PRVC-SIMV	Same
CPAP	Yes	CPAP	Same
PSV	Yes	PSV	Same
DuoLevel	Yes	DuoLevel	Same
APRV	Yes	APRV	Same
AMV	Yes	AMV	Same
VS	Yes	VS	Same

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
nCPAP	Yes	-	Different, same as secondary predicate device Evita XL(K083050)
PSV-S/T	Yes	PSV-S/T	Same
Apnea Ventilation	Yes	Yes	Same
Specifications - Ventilator setting parameter			
TV range	Adu: 100 to 4000 ml	Adu: 100 to 4000 ml	Same
	Ped: 20 to 300 ml	Ped: 20 to 300 ml	Same
	Neo: 2 to 100 ml	-	Different, similar to secondary predicate device Servo-U(K180098)
O2% range	Adu/Ped: 21 to 100 vol.%	21 to 100 vol.%	Same
	Neo: 21 to 100 vol.%	-	Different, same as secondary predicate device Evita XL(K083050)
f range	Adu/Ped: 1 to 100 /min	1 to 100 /min	Same
	Neo: 1 to 150 /min	-	Different, similar as secondary predicate device Evita XL(K083050)
fsimv range	Adu/Ped: 1 to 60 /min	1 to 60 /min	Same
	Neo: 1 to 60 /min	-	Different, similar to secondary predicate device Evita XL(K083050)
Tinsp range	Adu/Ped: 0.1 to 10 s	0.1 to 10 s	Same

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
	Neo: 0.1 to 10 s	-	Different, same as secondary predicate device Evita XL(K083050)
I:E range	Adu/Ped: 4:1 to 1:10	4:1 to 1:10	Same
	Neo: 4:1 to 1:10	-	Different, same as secondary predicate device Servo-U(K180098)
Tslope range	Adu/Ped: 0 to 2 s	0 to 2 s	Same
	Neo: 0 to 2 s	-	Different, same as secondary predicate device Evita XL(K083050)
△Pinsp range	Adu: 1 to 100 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	Adu: 1 to 100 cmH_2O	Same
	Ped: 1 to 95 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	Ped: 1 to 95 cmH_2O	
	Neo: 1 to 95 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	-	Different, similar to secondary predicate device Evita XL(K083050)
PEEP range	Adu/Ped: 0 to 50 cmH_2O	0 to 50 cmH_2O	Same
	Neo: 0 to 50 cmH_2O	-	Different, same as secondary predicate device Evita XL(K083050)
△Psupp range	Adu: 0 to 100 cmH_2O	Adu: 0 to 100 cmH_2O	Same

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
	Note: when backup air supply works, can set to up to 80cmH2O		
	Ped: 0 to 95 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	Ped: 0 to 95 cmH_2O	Same
	Neo: 0 to 95 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	-	Different, same as secondary predicate device Evita XL(K083050)
Phigh range	Adu/Ped: 0 to 95 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	0 to 95 cmH_2O	Same
	Neo: 0 to 95 cmH_2O Note: when backup air supply works, can set to up to 80cmH2O	-	Different, same as secondary predicate device Evita XL(K083050)
Plow range	Adu/Ped: 0 to 50 cmH_2O	0 to 50 cmH_2O	Same
	Neo: 0 to 50 cmH_2O	-	Different, same as secondary predicate device Evita XL(K083050)
Thigh range	Adu/Ped: 0.1 to 30 s	0.1 to 30 s	Same
	Neo: 0.1 to 30 s	-	Different, same as secondary predicate device Evita XL(K083050)
Tlow range	Adu/Ped: 0.2 to 30 s	0.1 to 30 s	Same
	Neo: 0.2 to 30 s	-	Different, similar to secondary predicate device Evita XL(K083050)

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
Tpause(%) range	Adu/Ped: OFF, 5% to 60%	OFF, 5% to 60%	Same
Flow range	Adu: 6 to 180 L/min	Adu: 6 to 180 L/min	Same
	Ped: 6 to 30 L/min	Ped: 6 to 30 L/min	
F-Trig range	Adu/ Ped: 0.5 to 15 L/min	0.5 to 15 L/min	Same
	Neo: 0.1 to 5 L/min	-	Different, similar to secondary predicate device Servo-U(K180098)
P-Trig range	Adu/ Ped: -20 to -1 cmH_2O	-20 to -1 cmH_2O	Same
	Neo: -20 to -1 cmH_2O	-	Different, same as secondary predicate device Servo-U(K180098)
Exp% range	Adu/ Ped:1 to 70%	1 to 70%	Same
	Neo: 1 to 70%	-	Different, same as secondary predicate device Servo-U(K180098)
MV% range	25 to 350%	25 to 350%	Same
Specifications - Ventilator monitoring parameter			
TV range	0 to 6000 ml	0 to 6000 ml	Same
TVspn range	0 to 6000 ml	0 to 6000 ml	Same
MV range	0 to 100 L/min	0 to 100 L/min	Same
MVspn range	0 to 100 L/min	0 to 100 L/min	Same
MVleak range	0 to 100 L/min	0 to 100 L/min	Same

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
FiO_2	15 to 100 vol.%	15 to 100 vol.%	Same
Airway pressure (Ppeak, Pplat, Pmean) range	-20 to 120 cmH_2O	-20 to 120 cmH_2O	Same
PEEP range	0 to 120 cmH_2O	0 to 120 cmH_2O	Same
ftotal/fspn/fmand range	0 to 200 /min	0 to 200 /min	Same
Tinsp range	0 to 60 s	0 to 60 s	Same
I:E range	99:1 to 1:99	99:1 to 1:99	Same
Leak% range	0 to 100%	0 to 100%	Same
RCexp range	0 to 10 s	0 to 10 s	Same
RSBI range	0 to 9999 1/(L•min)	0 to 9999 1/(L•min)	Same
WOBtot/ WOBvent/ WOBpat range	0 to 20 J/L	0 to 20 J/L	Same
Ri range	0 to 600 cmH_2O/(L/s)	0 to 600 cmH_2O/(L/s)	Same
Re range	0 to 600 cmH_2O/(L/s)	0 to 600 cmH_2O/(L/s)	Same
Cstat range	0 to 300 ml/cmH_2O	0 to 300 ml/cmH_2O	Same
Cdyn range	0 to 300 ml/cmH_2O	0 to 300 ml/cmH_2O	Same
TVe/IBW range	0 to 50 mL/kg	0 to 50 mL/kg	Same
NIF range	-45 to 0 cmH_2O	-45 to 0 cmH_2O	Same
P0.1 range	-20 to 0 cmH_2O	-20 to 0 cmH_2O	Same
PEEPi range	0 to 80 cmH_2O	0 to 80 cmH_2O	Same
PIF range	0 to 300 L/min	0 to 300 L/min	Same
PEF range	0 to 180 L/min	0 to 180 L/min	Same
Specifications - O2 Therapy			
Flow range	Adu: 10 to 60 L/min	-	Different, similar to secondary predicate device Servo-U(K180098)
	Ped: 2 to 25L/min	-	Different, similar to secondary predicate device Servo-U(K180098)
	Neo: 2 to 20 L/min	-	Different, similar to secondary predicate

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
			device Servo-U (K180098)
Specifications - Auxiliary Pressure			
PesI/PesE/ Paux2I/Paux2E range	-40 to 120 cmH_2O	-40 to 120 cmH_2O	Same
PtpI/PtpE range	-99 to 99 cmH_2O	-99 to 99 cmH_2O	Same
ΔPes range	-99 to 99 cmH_2O	-99 to 99 cmH_2O	Same
Specifications - ATRC			
Tube I.D.	2.5 to 12 mm	2.5 to 12 mm	Same
Compensate	1 to 100%	1 to 100%	Same
Specifications - Sigh			
Type	Pressure sigh	Pressure sigh	Same
△int.PEEP range	OFF,1 to 40 cmH_2O	OFF,1 to 40 cmH_2O	Same
Specifications – Apnea Ventilation			
Apnea Ventilation	Yes	Yes	Same
Specifications - Intellicycle			
Intellicycle	Yes	Yes	Same
Specifications - Lung Recruitment (SI)			
Pressure Hold	20 to 60 cmH_2O	20 to 60 cmH_2O	Same
Hold Time	10 to 40 s	10 to 40 s	
Specifications – Static PV Loop			
Pstart	0 to 50 cmH_2O	0 to 50 cmH_2O	Same
Flow	4 to 15 L/min	4 to 15 L/min	Same
Pmax	1 to 80 cmH_2O	1 to 80 cmH_2O	Same
Vlimit	100 to 2000 ml	100 to 2000 ml	Same
Specifications - Weaning Tools (SBT)			
Type	PSV ventilation	PSV ventilation	Same
SBT Criteria	Apnea Time	Apnea Time	Same

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
	High and low MV alarm High and low f alarm	High and low MV alarm High and low f alarm	
Specifications - Other Functions			
Manual Breath	Yes	Yes	Same
Expiration Hold	Yes	Yes	Same
Inspiration Hold	Yes	Yes	Same
Nebulization	Yes	Yes	Same
O_2↑ (Oxygen Enrichment)	Yes	Yes	Same
Suction	Yes	Yes	Same
Intrinsic PEEP	Yes	Yes	Same
Dynamic lung (PulmoSight)	Yes	Yes	Same
Specifications - Basic Alarm			
High/Low Minute Volume Alarm	Yes	Yes	Same
High/Low Tidal Volume Alarm	Yes	Yes	Same
High/Low f Alarm	Yes	Yes	Same
High/Low FiO_2 Alarm	Yes	Yes	Same
High/Low Airway Pressure Alarm	Yes	Yes	Same
Pressure Limiting Alarm	Yes	Yes	Same
Continuous Airway Pressure Alarm	Yes	Yes	Same
Apnea Alarm	Yes	Yes	Same
Specifications - Gas supply			
Pipeline supply	280 to 650 kPa for O_2, Air	280 to 650 kPa for O_2, Air	Same
Connector type	DISS body complying with CGA V-5	DISS body complying with CGA V-5	Same
Specifications – Sidestream CO_2 Module			

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
Module	External 1-slot Sidestream CO_2 Module 2.0	External 1-slot Sidestream CO_2 Module 2.0	Same
Water trap	DRYLINE II Water trap, Adult/pediatric	DRYLINE II Water trap, Adult/pediatric	Same
	DRYLINE II Water trap, Neonate	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
Sampling Line	DRYLINE Gas Sampling Line, Neonate 2.5 m	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
	DRYLINE Gas Sampling Line, Adult/pediatric 2.5 m	DRYLINE Gas Sampling Line, Adult/pediatric 2.5 m	Same
Airway adapter	Dryline airway adapter, straight	Dryline airway adapter, straight	Same
	Airway Adapter	Airway Adapter	Same
Sample flowrate	Neonate water trap: 90 ml/min	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
	Adult/pediatric water trap: 120 ml/min	Adult/pediatric water trap: 120 ml/min	Same
Measurement range	0 mmHg to 150 mmHg	0 mmHg to 150 mmHg	Same
Measurement accuracy	0 mmHg to 40 mmHg: ±2 mmHg 41 mmHg to 76 mmHg: ±5% of reading 77 mmHg to 99 mmHg: ±10% of reading 100 mmHg to 150 mmHg: ± (3mmHg + 8% of reading)	0 mmHg to 40 mmHg: ±2 mmHg 41 mmHg to 76 mmHg: ±5% of reading 77 mmHg to 99 mmHg: ±10% of reading 100 mmHg to 150 mmHg: ± (3mmHg + 8% of reading)	Same
Specifications – Mainstream CO_2 Module			

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
Module	External 1-slot Mainstream CO_2 Module	External 1-slot Mainstream CO_2 Module	Same
Sensor	CAPNOSTAT CO_2 sensor	CAPNOSTAT CO_2 sensor	Same
Airway adapter	Airway adapter, Adult/pediatric	Airway adapter, Adult/pediatric	Same
	Airway adapter, Neonate	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
Measurement range	0 mmHg to 150 mmHg	0 mmHg to 150 mmHg	Same
Measurement accuracy	0 mmHg to 40 mmHg: ±2 mmHg 41 mmHg to 70 mmHg: ±5% of reading 71 mmHg to 100 mmHg: ±8% of reading 101 mmHg to 150 mmHg: ±10% of reading	0 mmHg to 40 mmHg: ±2 mmHg 41 mmHg to 70 mmHg: ±5% of reading 71 mmHg to 100 mmHg: ±8% of reading 101 mmHg to 150 mmHg: ±10% of reading	Same
Specifications – Mindray SpO_2 Module			
Module	External 1-slot Mindray SpO_2 module	External 1-slot Mindray SpO_2 module	Same
Cable	7pin SpO_2 Cable	7pin SpO_2 Cable	Same
SpO2 sensor	SpO_2 sensor, finger-clip, adult	SpO_2 sensor, finger-clip, adult	Same
	SpO_2 sensor, finger-clip, pediatric	SpO_2 sensor, finger-clip, pediatric	Same
	SpO_2 sensor, foot, bandage	SpO_2 sensor, foot, bandage	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
SpO2 Measured parameters	Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode) 0% to 69%: Not specified	Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode)	Same

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
		0% to 69%: Not specified	
	Measurement range: 0 to 100% Accuracy: 70 to 100%: ±3% (neonate mode) 0% to 69%: Not specified	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
PR Measured parameters	Measurement range: 20 to 254 1/min; Accuracy: ±3 1/min.	Measurement range: 20 to 254 1/min; Accuracy: ±3 1/min.	Same
PI Measured parameters	Range: 0.05 to 20 %	Range: 0.05 to 20 %	Same
Specifications – Masimo SpO_2 Module			
Module	External 1-slot Masimo SpO_2 module	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
Cable	RD SET MD 14-05, PC 5 ft RD SET MD 14-12, Patient Cable 12 ft RD to LNC Adapter Cable LNCS to RD Adapter 8pin masimo Cable (RD SET) 8-pin Masimo SpO2 Extension Cable (MASIMOLNCS)	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
SpO2 sensor	LNCS DC-I Reusable sensor LNCS DC-IP Reusable SpO2sensor LNCS Multisite Reusable sensor LNCS Neo/Pt disposable sensor LNCS Neo disposable sensor LNCS Inf disposable sensor LNCS Pdtx adhesive sensor LNCS-Adtx disposable sensor	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
	LNCS Adtx disposable sensor LNCS Pdtx disposable sensor LNCS DCI reusable sensor LNCS DCIP reusable sensor LNCS NeoPt disposable sensor LNCS Neo disposable sensor LNCS Inf disposable sensor RD SET DCI, Adult Reusable Sensor RD SET DCIP, Pediatric Reusable Sensor RD Set TC-I SpO2 Reusable Tip-Clip Ear Sensor, 3ft RD SET Adhesive Sensor RD SET PDT Adhesive Sensor RD Set Infant Adhesive Sensor RD Set Neo Adhesive Sensor RD Set NeoPt Adhesive Sensor RD Set NeoPt-500 Non-adhesive sensor		
SpO2 Measured parameters	Range: 1 to 100% Accuracy: 70% to 100%: Adult/Pediatric: ±2% (without motion) Adult/Pediatric: ±3% (with motion) Neonate: ±3% 1 to 69%: not declaration. Low Perfusion (Pulse amplitude: >0.02%, Light penetration: >5%): Accuracy: ±2%	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
PR Measured parameters	Range: 25 to 240 1/min Accuracy:	-	Different, same as secondary predicate

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
	±3 1/min (without motion) ±5 1/min (with motion)		device BeneVision N Series Patient Monitors (K213799)
PI Measured parameters	Range: 0.02 to 20 %	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
Specifications – Nellcor SpO_2 Module			
Module	External 1-slot Nellcor SpO_2 module	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
Cable	8-pin, SpO2 extension cable, 2.5m	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
SpO2 sensor	Reusable SpO2 sensor, finger-clip, Adult Reusable Pediatric-Infant SpO2 sensor with wraps, Ped/Infant Reusable Adult/neonatal SpO2 sensor, adhesive wraps, Adult/Neo Nellcor MAX-A Disposable SpO2 sensor Nellcor MAX-P Disposable SpO2 sensor Nellcor MAX-I Disposable SpO2 sensor Nellcor MAX-N Disposable SpO2 sensor Nellcor reusable D-YS SpO2 sensor with wraps	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
SpO2 Measured parameters	Range: 0 to 100% Accuracy:	-	Different, same as secondary predicate device BeneVision N

Technical Characteristics	Subject device SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate SV600, SV800 Ventilator Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (K220107)	Comments
	70% to 100%: Adult/Pediatric: ±2% Neonate: ±3% 0 to 69%: not declaration.		Series Patient Monitors (K213799)
PR Measured parameters	Range: 20 to 300 1/min Accuracy: 20 to 250 1/min, ±3 1/min; 251 to 300 1/min: No declaration	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
PI Measured parameters	no declaration	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
WiFi module	SX-SDMAC-2832S+	-	Different, same as secondary predicate device BeneVision N Series Patient Monitors (K213799)
"-" means not applicable.			

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

7. PERFORMANCE DATA

To establish the substantial equivalence of the SV600 and SV800 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

Biocompatibility testing of the SV600, SV800 Ventilator was performed using the following standards:

- 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 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-17 Second edition 2023-09 Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18 Second edition 2020-01 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
- 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 SV600 and SV800 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 and Electrical Safety

EMC and Electrical Safety testing was performed using the following standards::

- 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

Bench Testing

To establish the substantial equivalence of the SV600 and SV800 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 demonstrated device performance using the following 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)

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 SV600 and SV800 Ventilators can be found substantially equivalent to the predicate device.