June 16, 2023

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

Re: K220107
Trade/Device Name: Mindray SV600 Ventilator, Mindray SV800 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: June 15, 2023
Received: June 16, 2023

Dear Yanhong Bai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

for James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220107

Device Name
SV600, SV800 Ventilator

Indications for Use *(Describe)*
The SV600, SV800 Ventilators are intended to be used in intensive care situations for long-term or during transport within a professional healthcare facility. The SV600, SV800 Ventilators are intended to provide ventilation assistance and breathing support for adult and pediatric patients with a minimum body weight of 10 kg (all pediatric subgroups except newborns (neonates)). The SV600, SV800 Ventilators 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.
Mindray Building, Keji 12th Road South High-tech Industrial Park,
Nanshan Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680

Contact: Contact Person: Yanhong Bai
Title: Manager Regulatory Affairs
Phone: +86 755 81885635
Fax: +86 755 26582680
E-mail: baiyanhong@mindray.com

Date Prepared: June 16, 2023

2. DEVICE

Device Trade Name:	SV600, SV800 Ventilator
Device Common Name:	Continuous ventilator
Classification Name:	21 CFR 868.5895, Continuous ventilator
Regulatory Class:	Class II
Primary Product Code:	CBK
Panel:	Anesthesiology

3. PREDICATE DEVICES

Primary predicate:

- K083050 - Evita XL Ventilator, Drager Medical AG & Co. KG

Secondary predicate:

- K202405 - 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 CO_2 Module and Accessories, SpO_2 Module and Accessories)

4. REFERENCE DEVICES

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

- K193228 - HAMILTON-G5 Ventilator, HAMILTON MEDICAL AG
- K180098 - Servo-U Ventilator, Maquet Critical Care AB
- K103211 - AVEA Ventilator, CareFusion
- K142679 - CARESCAPE R860 Ventilator, GE Healthcare Datex-Ohmeda, Inc.
- K201957 - A8, A9 Anesthesia System, ShenZhen Mindray Bio-Medical Electronics Co., Ltd.

5. 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.

6. INTENDED USE/INDICATIONS FOR USE

The SV600, SV800 Ventilators are intended to be used in intensive care situations for long-term or during transport within a professional healthcare facility. The SV600, SV800 Ventilators are intended to provide ventilation assistance and breathing support for adult and pediatric patients with a minimum body weight of 10 kg (all pediatric subgroups except newborns (neonates)). The SV600, SV800 Ventilators should be operated by properly-trained and authorized medical personnel. This equipment is not suitable for use in an MRI environment.

7. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Comparing with the primary predicate Evita XL Ventilator (K083050), 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 K202405 are incorporated into those ventilators with no changes to the modules. This predicate supports the CO_2 module and accessories and the SpO_2 module and accessories. 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 Evita XL Ventilator as cleared in K083050 and the BeneVision N Series Patient Monitors cleared in K202405.

Comparison of Technological Characteristics

The table below compares the key technological feature of the subject devices to the primary predicate device (Evita XL Ventilator (K083050)), secondary predicate devices and reference devices.

Technical Characteristics	**Subject device** **SV600, SV800 Ventilators** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(Subject device)**	**Primary predicate** **Evita XL Ventilator** **Drager Medical AG & Co. KG** **(K083050)**	**Comparison**
Ventilation mode			
V-A/C	Yes	CMV+Assist	Same
P-A/C	Yes	PCV+Assist	Same
PRVC	Yes	CMV+AutoFlow	Same
V-SIMV	Yes	SIMV	Same
P-SIMV	Yes	-	Different, same as reference device Servo-U(K180098)
PRVC-SIMV	Yes	SIMV+AutoFlow	Same
CPAP	Yes	CPAP	Same
PSV	Yes	Psupp	Same
DuoLevel	Yes	PCV+	Same
APRV	Yes	APRV	Same
AMV	Yes	-	Different, same as reference device G5(K193228)
VS	Yes	-	Different, same as reference device G5(K193228)
PSV-S/T	Yes	-	Different, same as reference device G5(K193228)
Apnea Ventilation	Yes	Yes	Same
Specifications - Ventilator setting parameter			
TV range	Adu: 100 to 4000 ml	Adu: 100 to 2000 ml	Similar
	Ped: 20 to 300 ml	Ped: 20 to 300 ml	Same
O2% range	21 to 100 vol.%	21 to 100 vol.%	Same
f range	1 to 100 1/min	0 to 100 1/min	Similar
fsimv range	1 to 60 1/min	0 to 100 1/min	Similar

Technical Characteristics	**Subject device** **SV600, SV800 Ventilators** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(Subject device)**	**Primary predicate** **Evita XL Ventilator** **Drager Medical AG & Co. KG** **(K083050)**	**Comparison**
Tinsp range	0.1 to 10 s	0.1 to 10 s	Same
I:E range	10:1 to 1:10	-	Different, same as reference device Servo-U(K180098)
Tslope range	0 to 2 s	0 to 2 s	Same
△Pinsp range	Adu: 1 to 100 cmH_2O	Adu: 0 to 95 cmH_2O	Similar
	Ped: 1 to 95 cmH_2O	Ped: 0 to 95 cmH_2O	Similar
PEEP range	0 to 50 cmH_2O	0 to 50 cmH_2O	Same
△Psupp range	Adu: 0 to 100 cmH_2O	Adu: 0 to 95 cmH_2O	Similar
	Ped: 0 to 95 cmH_2O	Ped: 0 to 95 cmH_2O	Same
Phigh range	0 to 95 cmH_2O	0 to 95 cmH_2O	Same
Plow range	0 to 50 cmH_2O	0 to 50 cmH_2O	Same
Thigh range	0.1 to 30 s	0.1 to 30 s	Same
Tlow range	0.2 to 30 s	0.1 to 30 s	Similar
Tpause(%) range	OFF, 5% to 60%	-	Different, same as reference device A8, A9(K201957)
Flow range	Adu: 6 to 180 L/min	Adu: 6-120 L/min	Similar
	Ped: 6 to 30 L/min	Ped: 6 to 30 L/min	Same
F-Trig range	0.5 to 15 L/min	0.3 to 15 L/min	Similar
P-Trig range	-20 to -1 cmH_2O	-	Different, same as reference device Servo-U(K180098)
Exp% range	1 to 70%	-	Different, same as reference device Servo-U(K180098)
MV% range	25 to 350%	-	Different, same as reference device G5(K193228)
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 120 L/min	Similar
MVspn range	0 to 100 L/min	0 to 120 L/min	Similar
MVleak range	0 to 100 L/min	0 to 99 L/min	Similar
FiO_2	15 to 100 vol.%	15 to 100 vol.%	Same

Technical Characteristics	**Subject device** **SV600, SV800 Ventilators** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(Subject device)**	**Primary predicate** **Evita XL Ventilator** **Drager Medical AG & Co. KG** **(K083050)**	**Comparison**
Airway pressure (Ppeak, Pplat, Pmean) range	-20 to 120 cmH_2O	-45 to 110 cmH_2O	Similar
PEEP range	0 to 120 cmH_2O	-45 to 110 cmH_2O	Similar
ftotal/fspn/fmand range	0 to 200 L/min	0 to 300 L/min	Similar
Tinsp range	0 to 60 s	-	Different, similar to reference device G5(K193228)
I:E range	99:1 to 1:99	-	Different, same as reference device G5(K193228)
Leak% range	0 to 100%	-	Different, same as reference device G5(K193228)
RCexp range	0 to 10 s	-	Different, samilar to reference device G5(K193228)
RSBI range	0 to 9999 1/(L•min)	0 to 9999 1/(L•min)	Same
WOBtot/ WOBvent/ WOBpat range	0 to 20 J/L	-	Different, same as reference device AVEA(K103211)
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)	-	Different, same as reference device G5(K193228)
Cstat range	0 to 300 ml/cmH_2O	0 to 300 ml/cmH_2O	Same
Cdyn range	0 to 300 ml/cmH_2O	-	Different, same as reference device AVEA(K103211)
TVe/IBW range	0 to 50 mL/kg	-	Different, samilar to reference device G5(K193228)
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	Yes	Similar
PIF range	0 to 300 L/min	-	Different, samilar to reference device G5(K193228)

Technical Characteristics	**Subject device** **SV600, SV800 Ventilators** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(Subject device)**	**Primary predicate** **Evita XL Ventilator** **Drager Medical AG & Co. KG** **(K083050)**	**Comparison**
PEF range	0 to 180 L/min	-	Different, samilar to reference device G5(K193228)
Specifications - Auxiliary Pressure			
PesI/PesE/ Paux2I/Paux2E range	-40 to 120 cmH_2O	-	Different, similar to reference device G5(K193228)
PtpI/PtpE range	-99 to 99 cmH_2O	-	Different, same as reference device G5(K193228)
ΔPes range	-99 to 99 cmH_2O	-	Different, similar to reference device AVEA(K103211)
Specifications - ATRC			
Tube I.D.	2.5 to 12 mm	2.5 to 12 mm	Same
Compensate	1 to 100%	0 to 100%	Similiar
Specifications - Sigh			
Type	Pressure sigh	Pressure sigh	Same
△int.PEEP range	OFF,1 to 40 cmH_2O	0 to 50 cmH_2O	Similar
Specifications – Apnea Ventilation			
Apnea Ventilation	Yes	Yes	Same
Specifications - Intellicycle			
Intellicycle	Yes	-	Different, same as reference device G5(K193228)
Specifications - Lung Recruitment (SI)			
Pressure Hold	20 to 60 cmH_2O	-	Different, same as reference device A8, A9(K201957)
Hold Time	10 to 40 s	-	Different, same as reference device A8, A9(K201957)
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)			

Technical Characteristics	**Subject device** **SV600, SV800 Ventilators** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** **(Subject device)**	**Primary predicate** **Evita XL Ventilator** **Drager Medical AG & Co. KG** **(K083050)**	**Comparison**
Type	PSV ventilation	-	Different, same as reference device CARESCAPE R860(K142679)
SBT Criteria	Apnea Time High and low MV alarm High and low f alarm	-	Different, same as reference device CARESCAPE R860(K142679)
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	-	Different, same as reference device G5(K193228)
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			

Technical Characteristics	Subject device SV600, SV800 Ventilators Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate Evita XL Ventilator Drager Medical AG & Co. KG (K083050)	Comparison
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 - Modules			
Specifications – Sidestream CO_2 Module	Yes	-	Different, same as secondary predicate BeneVision N Series Patient Monitors(K202405)
Specifications – Mainstream CO_2 Module	Yes	Yes	Same
Specifications – SpO_2 Module	Yes	-	Different, same as secondary predicate BeneVision N Series Patient Monitors(K202405)
"-" means not applicable.			

Discussion of technological characteristics that are not the same as the predicate device

The differences between the subject device and predicate device are identified in the table above. Many of the differences, when compared to the predicate, are the same or similar to the identified reference devices as noted in the table. Other identified differences are still similar to the predicate device in that the ranges for the parameters are within the ranges of the predicate device, including but not limited to: MV range, MVspn range, △Pinsp range for pediatrics, and airway pressure. Other parameters that are similar, such as MVleak range and △Pinsp range for adults, differ only by a small amount that do not have a clinically meaningful impact.

In conclusion, the subject and predicate have similar technological characteristics and intended uses. Performance testing supports substantial equivalence.

8. 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

The SV600 and SV800 Ventilators were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification of the 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

The SV600 and SV800 Ventilators were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- AIM Standard 7351731 Rev. 3.00 2021-06-04 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
- 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 2.1 2012-11 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- ISO 80601-2-12 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 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 2.1 2012-11 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 80601-2-12 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 5356-1:2015 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
- CGA V-5:2008 (Reaffirmed 2013) Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)
- EN 13544-2:2002+A1:2009 Respiratory therapy equipment-Part 2: Tubing and connectors

- ASTM F1100-90 (Reapproved 1997) Standard Specification for Ventilator Intended for Use in Critical Care (only Endurance Testing)

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