



October 31, 2024

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

Re: K240375

Trade/Device Name: V80 Anesthetic Vaporizer (V80)

Regulation Number: 21 CFR 868.5880

Regulation Name: Anesthetic Vaporizer

Regulatory Class: Class II

Product Code: CAD

Dated: September 30, 2024

Received: September 30, 2024

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 (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,

Bradley Q. Quinn -S

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

Enclosure

Indications for Use

510(k) Number (if known)
K240375

Device Name
V80 Anesthetic Vaporizer

Indications for Use (Describe)

V80 Anesthetic Vaporizer is used to enrich the fresh gas flow of an anesthesia delivery system with controllable desflurane vapour.

V80 Anesthetic Vaporizer is intended to be operated only by licensed clinicians and qualified anesthesia personnel who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on the anesthetic vaporizer.

V80 Anesthetic Vaporizer cannot be used in mobile vehicles, airplanes, helicopters or ships.

V80 Anesthetic Vaporizer 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.

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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 V80 Anesthetic Vaporizer is provided below.

1. SUBMITTER

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Date Prepared: Oct 30, 2024

2. DEVICE

Device Trade Name: V80 Anesthetic Vaporizer
Device Common Name: Vaporizer, Anesthesia, Non-heated
Classification Name: 21 CFR 868.5880, Class II, Anesthetic Vaporizer
Regulatory Class: Class II
Primary Product Code: CAD

3. PREDICATE DEVICES

Primary predicate:

- K042276 – D-Vapor Anesthetic Vaporizer, Draeger Medical AG & Co KGaA

4. REFERENCE DEVICES

- K000275 – DATEX-OHMEDA TEC 6 PLUS ANESTHETIC VAPORIZER, DATEXOHMEDA TEC 6 PLUS NAD VARIANT ANESTHESIA, DATEX-OHMEDA, INC.
- K150167 –V60 Anesthetic Vaporizer, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
- 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.

5. DEVICE DESCRIPTION

V80 Anesthetic Vaporizer is used to provide desflurane vapour with controllable concentration.

6. INTENDED USE/INDICATIONS FOR USE

V80 Anesthetic Vaporizer is used to enrich the fresh gas flow of an anesthesia delivery system with controllable desflurane vapour.

V80 Anesthetic Vaporizer is intended to be operated only by licensed clinicians and qualified anesthesia personnel who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on the anesthetic vaporizer.

V80 Anesthetic Vaporizer cannot be used in mobile vehicles, airplanes, helicopters or ships.

V80 Anesthetic Vaporizer is not suitable for use in an MRI environment.

7. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Comparing with the primary predicate D-Vapor Anesthetic Vaporizer (K042276), the indications for use for the subject device V80 Anesthetic Vaporizer is the same.

Comparison of Technological Characteristics

The table below compares the technology characteristics and performance specifications of the subject device V80 Anesthetic Vaporizer to the predicate D-Vapor Anesthetic Vaporizer (K042276).

Technical Characteristics		Subject device V80 Anesthetic Vaporizer Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate D-Vapor Anesthetic Vaporizer D-Vapor Anesthetic Vaporizer, Draeger Medical AG & Co (K042276)
Performance			
Control parameter	Concentration setting range	2vol.% to 18 vol.%	2vol.% to 18 vol.%
	Calibrated setting concentration	±0.5vol.% or ±15%rel, the larger value applies in each case	±0.5vol.% or ±15%rel, the larger value applies in each case
	Other setting concentration	±0.9Vol.% or ±30% rel, which is greater (at 0.2 to 2L/min); ±0.9Vol.% or ±20% rel, which is greater (at 2 to 8L/min); ±0.9Vol.% or ±30% rel, which is greater (at 8 to 15L/min);	±0.9Vol.% or ±30% rel, which is greater (at 0.2 to 2L/min); ±0.9Vol.% or ±20% rel, which is greater (at 2 to 8L/min); ±0.9Vol.% or ±30% rel, which is greater (at 8 to 15L/min);
Flow range		0.2 to 15L/min	0.2 to 15L/min
Maximum tilt angle during working		10°	10°
Warm-up time at 22 °C		within 6 min	within 6 min
User interface			
Display Panel	Indicator	Operational	Operational
		No Output	No Output
		Delivery Low	Delivery Low
		Fill Up	Fill Up
		Battery	Battery
	Glass tube liquid level indicator	A sight glass on the front of the device to visually indicate the level of agent	A sight glass on the front of the device to visually indicate the level of agent
Audio Paused		120s	120s
Connection to anesthesia delivery system			
Connection to anesthesia delivery system		Selectatec®-compatible plug-in connectors	Selectatec®-compatible plug-in connectors
Filling system			
Filling system		Saf-T-Fill™	Saf-T-Fill™
Filling volume		Total:320 mL	Total:300 mL
Anesthetic agent loss (24 hours in storage)		≤ 0.5mL(22°C)	≤ 0.5mL(22°C)
Anesthetic agent loss (24 hours in work)		≤ 2.5mL(22°C)	≤ 2.5mL(22°C)

Technical Characteristics		Subject device V80 Anesthetic Vaporizer Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Subject device)	Primary predicate D-Vapor Anesthetic Vaporizer D-Vapor Anesthetic Vaporizer, Draeger Medical AG & Co (K042276)
Filling time for one anesthetic agent bottle of Desflurane (240 mL)	At 22 °C and with the Vapor not yet warmed up	< 1 minute	< 1 minute
	At 22 °C and with a warmed-up Vapor, the filling time is increased.	< 2 minutes	< 2 minutes
Internal Battery			
Battery		Li-ion (sealed) battery	Nickel/metal hydride (NiMH)
Bridging time when mains power supply absent		6 minutes (at a concentration of 6 Vol.% maximum, fresh-gas flow 4 L/min and fully charged battery)	maximum of 5 minutes (at a concentration of 6 Vol.% maximum, fresh-gas flow 4 L/min and fully charged battery)

The differences in technological characteristics do not raise new questions of safety and effectiveness.

8. PERFORMANCE DATA

To establish the substantial equivalence of the V80 Anesthetic Vaporizer, Mindray conducted functional and system level testing on the subject device. The testing provided an evaluation of the performance of the device relevant to each of the differences between the subject device and the predicate device. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.

Mindray has conducted testing to ensure the subject device meets relevant consensus standards.

Biocompatibility Testing

V80 Anesthetic Vaporizer is categorized as externally communicating, indirect contact with tissue, limited contact duration (≤ 24 hours).

The biocompatibility tests performed on the subject device including Particulate matter test (ISO 18562-2:2017), Volatile organic compounds (VOCs) test (ISO 18562-3:2017) and Inorganic gases test

The V80 Anesthetic Vaporizer 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 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 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 " [Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff](#)". Verification of the V80 Anesthetic Vaporizer was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

The level of concern for the V80 Anesthetic Vaporizer software was determined to be Major in that the Software Device is a life-sustaining device that provides vital signs monitoring and alarms for potentially life-threatening situations for which medical intervention is necessary.

The V80 Anesthetic Vaporizer consists of the following two software subcomponents:

- 1) Control subsystem
- 2) Protection subsystem

Electromagnetic Compatibility and Electrical Safety

The V80 Anesthetic Vaporizer was 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 (edition 3.2) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI IEC ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & 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 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
- IEC 60601-1-6 Edition 3.2 2020-07 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
- 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

Bench Testing

To establish the substantial equivalence of the V80 Anesthetic Vaporizer, Mindray conducted functional and system level testing on the device. The results of the bench testing show that the subject device meets its accuracy specification and is substantially equivalent to the predicate device.

In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.

- ISO 80601-2-13 First edition 2011-08-11 Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]
- ISO 5360 Fourth edition 2016-02-15 Anaesthetic vaporizers - Agent specific filling systems

Shelf life

No shelf life is claimed

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 V80 Anesthetic Vaporizer can be found substantially equivalent to the predicate devices.