April 14, 2026

Iconic Solutions by Murcia, SL
% Dulciana Chan
Contract Consultant
RQM+
5000 Centregreen Way Suite 100, Cary, NC 27513 USA

Re: K252663
Trade/Device Name: INBENTUS VERSATILE
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: March 17, 2026
Received: March 17, 2026

Dear Dulciana Chan:

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

Ethan Nyberg, Ph.D.
Assistant Director, Respiratory Devices Team
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)*
K252663

Device Name
INBENTUS VERSATILE

Indications for Use *(Describe)*
The INBENTUS VERSATILE ventilator is intended to provide invasive and noninvasive ventilatory support to adult, pediatric, and neonatal patients.

It is only intended for use by qualified health care personnel, within professional hospital facilities and to transport patients within those facilities.

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

DATE PREPARED
April 7, 2026

MANUFACTURER AND 510(k) OWNER
ICONIC SOLUTIONS BY MURCIA, SL
Calle Central, 13, 1ºC
30100, Murcia, Spain
Telephone: +34 968 96 52 72
Official Contact: Antonio Alarcón Miñarro, QA & RA Manager

DEVICE INFORMATION

Proprietary Name/Trade Name:	INBENTUS VERSATILE
Common Name:	Continuous Ventilator
Regulation Number:	21 CFR 868.5895
Class:	II
Product Code:	CBK
Review Panel:	Anesthesiology

PREDICATE DEVICE IDENTIFICATION
The INBENTUS VERSATILE is substantially equivalent to the following predicate device:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K201658	Hamilton-C6 / Hamilton Medical AG	✓

DEVICE DESCRIPTION
The INBENTUS VERSATILE is a multi-purpose ventilator for patients requiring ventilatory support. It is intended to be used only by qualified medical staff within professional hospital facilities, or by qualified medical staff during the transport of patients within the hospital facility. The INBENTUS VERSATILE ventilator is independent of hospital compressed air systems and can provide both invasive (via endotracheal tube) and non-invasive (via mask) ventilation for adult, pediatric, and neonatal patients throughout their hospital stay.

INDICATIONS FOR USE
The INBENTUS VERSATILE ventilator is intended to provide invasive and noninvasive ventilatory support to adult, pediatric, and neonatal patients.

It is only intended for use by qualified health care personnel, within professional hospital facilities and to transport patients within those facilities.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
ICONIC SOLUTIONS BY MURCIA, SL believes that the INBENTUS VERSATILE is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use as the primary predicate device cleared in K201658 and similar indications for use. Both devices are intended to be used in the same environment (i.e., healthcare facilities) and in the same patient populations (i.e., adult, pediatric and neonatal patients). The subject device has similar design and dimensions to the predicate device, and both devices include similar functions and performance specifications.

The main differences with the primary predicate are the absence of optional functionalities including high flow therapy, pulse oximetry, and capnography in the subject device. The absence of these functions does not impact the intended use and conditions of use of the device. The technological characteristics of the subject device have undergone testing to ensure the device is substantially equivalent to the predicate. A comparative summary of the technological characteristics of the subject and predicate device is presented in the table below.

Technical Characteristic	Subject device: INBENTUS VERSATILE	Predicate device: Currently marketed HAMILTON-C6 K201658	Comparison
Intended use	The INBENTUS VERSATILE ventilator is intended to provide invasive and non-invasive ventilatory support to adult, pediatric, and neonatal patients. It is only intended for use by qualified health care personnel, within professional hospital facilities and to transport patients within those facilities.	The HAMILTON-C6 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics and optionally infants and neonates. Intended areas of use: • In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room • During transfer of ventilated patients within the hospital. The HAMILTON-C6 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	Identical.
Product classification code	CBK	CBK	Identical.
CFR citation	21 CFR 868.5895	21 CFR 868.5895	Identical.

Technical Characteristic	Subject device: INBENTUS VERSATILE	Predicate device: Currently marketed HAMILTON-C6 K201658	Comparison
Principal operator	Qualified, trained personnel under the direction of a physician.	Qualified, trained personnel under the direction of a physician.	**Identical.**
Environment of use	To be used in professional hospital facilities and to transport patients within those facilities.	Intended areas of use: Health care facilities During transfer of ventilated patients within health care facilities	**Identical.**
Intended patient population	Adult, pediatric, and neonatal patients.	Adults and pediatrics and optionally infants and neonates.	**Identical.**
Device Configuration	INBENTUS VERSATILE ventilator features a 15.6-inch touch screen monitor and a ventilation unit. The system is compact to adapt to different ICU configurations.	HAMILTON-C6 includes a 17-inch touchscreen panel and the ventilation unit. HAMILTON-C6 offers flexible device configuration: mounted on trolley, shelf-mounted option…	**Substantially Equivalent.**
Method of supply gas pressurization	Internal turbine for air, compressed source for O2.	Internal turbine for air, compressed source for O2.	**Identical.**
Power source	AC. Battery (x2).	AC. Battery (x2)	**Identical.**
Battery	Lithium-ion Up to 2.5h with 1 battery, Up to 5h with 2 batteries.	Lithium-ion > 1.5h 1 battery, > 3h 2 batteries.	**Substantially Equivalent.**
Supply gas	High Pressure Oxygen, Ambient air.	High Pressure Oxygen, Ambient air.	**Identical.**
Therapy Types	Invasive ventilation Non-invasive ventilation	Invasive, Non-invasive, HiFlowO2.	**Substantially Equivalent.** High Flow Oxygen therapy not included in subject device.
Patient interface	Provide invasive ventilation (via endotracheal tube, ET o tracheal tube, TT tube) and non-invasive ventilation and breathing support (via mask).	Delivered invasively ventilation (via endotracheal tube, ET o tracheal tube, TT tube) or noninvasively (via mask).	**Identical.**

Technical Characteristic	Subject device: INBENTUS VERSATILE				Predicate device: Currently marketed HAMILTON-C6 K201658				Comparison
Operating Ventilation Modes (For adults (A), pediatrics (P), and neonates (N))	Mode	A	P	N	Mode	A	P	N	
	Invasive Ventilation								
	VC-CMV	x	x	-	(S)CMV	x	x	-	SE
	VC-ACV	x	x	-	(S)CMV	x	x	-	SE
	VC-SIMV	x	x	-	SIMV	x	x	-	SE
	(PC-CMV)+PCVR	x	x	x	APVcmv/(S)CMV+	x	x	x	SE
	(PC-ACV)+PCVR	x	x	x	APVcmv/(S)CMV+	x	x	x	SE
	(PC-SIMV)+PCVR	x	x	x	APVsimv/SIMV+	x	x	x	SE
	PC-CMV	x	x	x	PCV+	x	x	x	SE
	PC-ACV	x	x	x	PCV+	x	x	x	SE
	PC-SIMV	x	x	x	PSIMV+	x	x	x	SE
	PC-SIMV+	x	x	x	DouPAP	x	x	x	SE
	PC-APRV	x	x	x	APRV	x	x	x	SE
	SPN-CPAP	x	x	x	SPONT	x	x	x	SE
	--				ASV	o	o		Not included in subject device
	Non-Invasive Ventilation								
	(NIV) SPN-CPAP	x	x	x	NIV & nCPAP-PS	x	x	x	SE
	--	x	x	x	NIV-ST	x	x	x	Not included in subject device
	Legend: x : Available; - : Not available; o : Optional								
Performance	Conformance to ISO 80601-2-12 requirements on essential performance of critical care ventilators. Waveform comparison tests with predicate device.				Conformance to ISO 80601-2-12 requirements on essential performance of critical care ventilators				Substantially Equivalent
Device Safety Measures	In case of a power supply, technical, or pneumatics failure, the INBENTUS VERSATILE ventilator includes several redundant mechanical safety systems that allow for reducing and limiting airway				In case of a power supply, technical, or pneumatics failure the ambient valve allows spontaneous breathing.				Substantially equivalent

Technical Characteristic	Subject device: INBENTUS VERSATILE	Predicate device: Currently marketed HAMILTON-C6 K201658	Comparison
	pressure and enabling the patient's spontaneous breathing		
Calibrations and pre-operational checks	Compliance and leakage test	Leakage Test	**Substantially equivalent**
	Resistance Test	Resistance Test (Step 1 of Patient Flow Sensor Test)	**Substantially equivalent**
	Patient Flow Sensor Test (Two Steps)	Patient Flow Sensor Test (Two Steps)	**Substantially equivalent**
	Oxygen Concentration Sensor calibration Test	Oxygen Concentration Sensor calibration Test	**Substantially equivalent**
User Interface, Screens and functions	Alarm banner Alarm silence key Monitored Parameters Waveforms and Loops Events Log Screenshots, video, log	Alarm message bar Alarm silence key Monitored Parameters Waveforms and Loops Events Logs Screenshots, log	**Substantially Equivalent**
Alarms and monitoring	High, medium, and low alarm priorities Optical and acoustical alarm indication Adjustable alarm limits	High, medium, and low alarm priorities Optical and acoustical alarm indication Adjustable alarm limits	**Substantially Equivalent**
Tools and ventilation maneuvers	Mode / A / P / N	Mode / A / P / N	Comparison
	Inspiratory hold / x / x / x	Inspiratory hold / x / x / x	**SE**
	Expiratory hold / x / x / x	Expiratory hold / x / x / x	**SE**
	P0.1 Meas. / x / x / x	P0.1 Meas. / x / x / x	**SE**
	PEEPi Meas. / x / x / x	AutoPEEP Meas / x / x / x	**SE**
	O2 Boost / x / x / x	Oxygen Enrich. / x / x / x	**SE**
	Alveolar recr. / x / x / x	Recruitment / x / x / x	**SE**
	Sigh / x / x / -	Sigh / x / x / -	**SE**
	Legend: x : Available; - : Not available		
Nebulizer	Pneumatic Nebulizer	Pneumatic Nebulizer Electronic (Option)	**Substantially equivalent for included parts.**
External devices and sensors options	Humidifier	Electr.Controlled Hum.(Op) Intellicuff (Option) CO2 MainStream (Option)	**Substantially equivalent for included parts.**

Technical Characteristic	Subject device: INBENTUS VERSATILE	Predicate device: Currently marketed HAMILTON-C6 K201658	Comparison
		CO2 SideStream (Option) SpO2 (Option)	

SUMMARY OF NON-CLINICAL TESTING
The following tests were performed to demonstrate substantial equivalence based on current industry standards.

Biocompatibility:
Biocompatibility evaluation of the gas pathway was conducted according to ISO 18562-1 and FDA's Biocompatibility Guidance. Testing included:
- Particulate matter (PM) emissions per ISO 18562-2
- Volatile organic compound (VOC) emissions per ISO18562-3

Software/Cybersecurity:
Software verification and validation testing was performed per IEC 62304 *Medical device software – Software life cycle processes to demonstrate safety* and performance based on current industry standards.

Electrical, Mechanical, and Thermal Safety, and Electromagnetic Compatibility:
The subject device has been designed to conform to the following standards covering electrical, mechanical, and thermal safety and EMC:
- IEC 60601-1
- IEC 60601-1-2
- IEC TR 60601-4-2

Performance Testing:
The following tests were performed on the INBENTUS VERSATILE:
- System Level Performance Verification Testing
- Alarm Safety and Performance Testing per IEC 60601-1-8
- Basic Safety and Essential Performance of Critical Care Ventilators per ISO 80601-2-12
- Basic Safety and Essential Performance of Respiratory Gas Monitors per ISO 80601-2-55
- Waveform Comparison Test with predicate device
- Use-Life Reliability Testing
- Usability Study per IEC 62366-1

CONCLUSION
Based on the testing performed including biocompatibility, software and cybersecurity, electrical safety, electromagnetic compatibility, usability and performance testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the

predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed INBENTUS VERSATILE ventilator are assessed to be substantially equivalent to the primary predicate device.