Weinmann Emergency Medical Technology GmbH + Co. KG
Kristin Ratschiller
Team Leader QMS/ RA, Supply Chain + Quality Management
Frohbösestraße 12
Hamburg, 22525 De

Re: K193191
Trade/Device Name: MEDUMAT Easy CPR, MEDUMAT Easy CPR with bag
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: October 22, 2020
Received: October 22, 2020

Dear Kristin Ratschiller:

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,

Brandon Blakely, PhD
Assistant Director (Acting)
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193191

Device Name
MEDUMAT Easy CPR

Indications for Use *(Describe)*
MEDUMAT Easy CPR is an electrical, pneumatically operated emergency and transport ventilator used for ventilation and oxygen inhalation with either a mask or tube.

Patient groups
Adults and children with a body weight of over 22 lbs (10 kg) where spontaneous respiration has failed or is inadequate.

Users
Qualified medical personnel only

Intended environments of use
• Mobile use for emergency medicine and primary care during emergency deployments
• During land or air transport or transfer between hospital rooms and departments

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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K193191 - 510(k) Summary

Applicant

Company Name	WEINMANN Emergency Medical Technology GmbH + Co. KG
Address	Frohbösestraße 12 22525 Hamburg Germany
Establishment No.	Not known yet – first application

Official contact person

Name	Kristin Ratschiller
Company Name	WEINMANN Emergency Medical Technology GmbH + Co. KG
Address	Frohbösestraße 12 22525 Hamburg Germany
Establishment No.	Not known yet – first application
Department	QM-Systems + Regulatory Affairs
Phone	+49 40 88 18 96-149
Email	ra@weinmann-emt.de

Subject device

Device Classification Name	Ventilator, Emergency, Powered (Resuscitator)
510(k) number	K193191
Device Name	MEDUMAT Easy CPR
Applicant	WEINMANN Emergency Medical Technology GmbH + Co. KG
Regulation Number	868.5925
Classification Product Code	BTL

Predicate device

Device Classification Name	Ventilator, Emergency, Powered (Resuscitator)
510(k) number	K051322
Device Name	Pneupac VR1 Standard
Applicant	Smiths Medical International, LTD.
Regulation Number	868.5925
Classification Product Code	BTL
Class	II

Date of Submission	2020-11-20
Device Identification:	
Device Name	MEDUMAT Easy CPR
Common Name	Emergency and Transport Ventilator
Model Number	WM 20310/ WM 20330

Subject Device Classification:	
Regulation Description	Powered Emergency Ventilator
Product Code	BTL
C.F.R. Section	868.5925
Classification Panel	Anesthesiology Devices
Device Class	Class II

Device Description:

MEDUMAT Easy CPR is an electrical, pneumatically operated emergency and transport ventilator. Highly compressed medical oxygen is used as the ventilation gas; this is reduced to the necessary operating pressure via an external pressure reducer. The oxygen is supplied at the compressed gas connection. The ventilation parameters – frequency and tidal volume – are linked together and can be set using the adjusting knob on the device. The ventilation gas is transported to the patient through the ventilation hose via the patient valve and ventilation mask or via the tube. The lip membrane in the patient valve allows the patient exhalation of expiration gas. In order to monitor the patient, the device features continuous measurement of the airway pressure as well as a visual and audible alarm system.

Indications for Use:

MEDUMAT EasyCPR is an electrical, pneumatically operated emergency and transport ventilator used for ventilation and oxygen inhalation with either a mask or tube.

Patient groups:
Adults and children with a body weight of over 22 lbs (10 kg) where spontaneous respiration has failed or is inadequate.

Users:
Qualified medical personnel only

Intended environments of use :

- Mobile use for emergency medicine and primary care during emergency deployments
- During land or air transport or transfer between hospital rooms and departments

Comparison of the Subject Device and the Predicate Device

The following table presents the comparison and brief discussion of technological characteristics, functions, and parameters of the identified predicate device and the proposed device.

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
Intended Use / Indications for Use	MEDUMAT Easy CPR is an electrical, pneumatically operated emergency and transport ventilator used for ventilation and oxygen inhalation with either a mask or tube. Patient groups: Adults and children with a body weight of over 22 lbs (10 kg) where spontaneous respiration has failed or is inadequate. Users: Qualified medical personnel only Intended environments of use • Mobile use for emergency medicine and primary care during emergency deployments	The Pneupac VR1 range are hand held portable, time cycled, gas powered generator ventilatory resuscitators that are suitable for emergency and transport use and will operate safely in an MRI environment up to 3 Tesla. They are designed for use by qualified medical caregivers, paramedics and other trained personnel for the following conditions: Pneupac VR1 Standard – Ventilatory resuscitator intended for use on adults and children above a bodyweight of 22 lb (10kg) with either respiratory distress/insufficiency or no respiratory function.	Similar	The subject device and the predicate device are intended to be used for similar medical indications and have the same general purpose and operation modes. Both devices are intended to be used as emergency and transport ventilators. One difference is that the predicate device is intended for use in an MRI environment. The subject device is not intended for MRI environment use and is not MRI safe. Since the subject device is not intended for MRI use and is not labeled as MRI safe, no additional concerns of safety are raised.

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
	• During land or air transport or transfer between hospital rooms and departments Contraindications: None currently known. Possible side effects and complications: • Undesirable effects on the cardiovascular system (e.g. reduction of cardiac output, reduction of venous return flow) • Drying out of the airways • Overinflation of the lung tissue (lung rupture) • Overinflation of the stomach during mask ventilation (e.g. aspiration of stomach contents) Exclusions and restrictions of intended use			

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
	The device is not approved for the following applications: • Operation for long-term ventilation in excess of 24 hours • Operation in hyperbaric chambers • Operation in combination with magnetic resonance scanners (MRI, NMR, NMI)			
Operating principle /Control mechanism	Time cycled, volume controlled, pressure limited flow generator	Time cycled, volume controlled, pressure limited flow generator.	Similar	The operating principles of the subject device and the predicate device are identical and only differ slightly in wording and underlying control mechanisms. Both devices are oxygen driven.
Patient population	Adults and children above a bodyweight of 22 lb (10 kg)	Adults and children above a bodyweight of 22 lb (10 kg)	Identical	-
Environment of use	• Mobile use for emergency medicine and primary care during emergency deployments • During land or air transport or transfer between hospital rooms and departments	Inside and outside hospital in emergency situations and for intra- and interhospital transport and for operation in an MRI environment up to 3 Tesla.	Different	As an additional feature, the predicate device is suitable for the operation in an MRI up to 3 Tesla. The use in an MRI or a hyperbaric chamber is excluded in the IFU for the subject device.

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
Excluded Environment of use	• Operation in hyperbaric chambers • Operation in combination with magnetic resonance scanners (MRI, NMR, NMI)	• No information about the use in a hyperbaric chamber available • MRI environment not excluded	Different	
Contraindications	None currently known.	Not specified	Identical	-
Principle operator / intended user	Qualified medical personnel only	Medical personnel, paramedics and ambulance technicians	Similar	Both subject device and predicate device are only intended to be used by qualified medical personnel.
Dimensions	Height: 5.7 inch (145 mm) Width: 3.9 inch (100 mm) Depth: 3.5 inch (90 mm)	Height: 6.7 inch (170 mm) Width: 3.7 inch (95 mm) Depth: 3.9 inch (100 mm)	Different	The dimensions of the subject and the predicate device differ slightly.
Weight	1.5 lbs (0.7 kg)	0.9 lbs (0.42 kg)	Similar	The weight of the subject device is higher than the predicate device. With regards to the intended use and organization of the device as a mobile device, these differences will not have any impact on the safety and effectiveness not the operation and handling of the device.

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
Operational modes/Ventilation modes			Different	The subject device has the same operational/ventilation modes as the predicate device. Most of the specifications for these modes are identical. The tidal volume and the inspiration-expiration time ratio are similar, the max. ventilation pressure setting range and the relief pressure are different for the subject and the predicate device, but no additional concerns are introduced through that. In addition to this, monitoring of the ventilation pressure is added in compliance with the requirements of the standard DIN EN 794-3:2009-12.
Automatic volume controlled ventilation	Yes	Yes	Identical	
Manual volume controlled ventilation	Yes	Yes	Identical	
Demand flow mode	Yes	Yes	Identical	
Tidal Volume(Vt)	65 to 950 ml	150 to 1050 ml	Similar	
Ventilation rate (freq.) setting range	10 to 25 bpm	10 to 25 bpm	Identical	
Fixed combination of tidal volume and ventilation rate	Yes	Yes	Identical	
Inspiratory-expiratory time ratio (I:E)	1:2 (Vt ≤ 150 ml), 1:3 (Vt > 150 ml) 1:1 (manual mode)	1:2 fixed in continuous mode 1:2 manual mode	Similar	
Max. ventilation pressure setting range	20 or 45 cmH_2O	40 cm H_2O (standard) 60 cmH_2O (optional)	Different	
Relief pressure (single fault)	max. 100 cmH_2O	40 cm H_2O (standard) 60 cmH_2O (optional)	Different	
O_2 concentration	100% O_2	100% O_2	Identical	
Monitoring	Ventilation pressure monitoring	None	Different	

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
Alarms	High Airway Pressure Low Airway Pressure Low gas supply Low battery	High Airway Pressure - - -	Different	Both, subject and predicate devices have an alarm for high airway pressure, however, the alarm generation differs. Furthermore, the subject device has some additional alarms to increase the safety of the device.
Tidal volume (Vt) accuracy	STP: 65 to 950 ml (± 40 ml or ± 20%) The larger tolerance applies.	STP conditions: ±15% Vt (no-air-Mix)	Similar	The comparison of the tidal volume specifications shows that the tolerances for tidal volume accuracy for the predicate device are similar to the tolerances of the subject device.
Supply gas	Medical oxygen	Medical oxygen	Identical	-
Permitted operating pressure for oxygen source	40 to 87.0 psi (2.7 to 6.0 bar)	40 to 150 psi (2.7 to 10,34 bar)	Similar	The lower inlet pressure levels of the predicate and the subject device are identical, but the upper inlet pressure limit differs. No additional concerns of safety are introduced.
Minimum necessary flow of oxygen source	40 l/min	65l/min	Similar	The specifications of the subject device differ from the specifications of the predicate device with respect to the minimum required gas flow.
Power supply	3,6V lithium battery	None	Different	The predicate device is pneumatically driven and does not need an internal battery. The battery specifications for the subject device have been tested. Therefore, no additional concerns of safety are introduced.
Operating conditions			Similar	The operating conditions are similar and tested for the subject device.
Temperature range	-4° to 122° F (-20 °C to +50 °C)	-0,4°F to 122°F (-18°C to +50° C)	Similar	
Air pressure	62 kPa to 110 kPa	70 kPa to 110kPa	Similar	
Humidity	Max. 95% RH without condensation	40-95% relative humidity	Similar	

Feature	subject device MEDUMAT Easy CPR (K193191)	predicate device Pneupac VR1 Standard (K051322)	Comparison	Discussion
Connectors			Similar	Patient connections and compressed gas connections are identical between subject and predicate device. The patient valve resistance differs slightly.
Patient connection at patient valve	15 mm internal tapered connector 22 mm external tapered connector	15 mm internal tapered connector 22 mm external tapered connector	Identical	
Compressed gas connection	External thread CGA 1240 (9/16” DISS connection)	9/16” DISS connection	Identical	
Patient valve resistance	Inspiration: <6 cmH_2O at 30 l/min to 60 l/min Expiration: <6 cmH_2O at 30 l/min to 60 l/min	< 4.5 mbar at 50 l/min < 3.0 mbar at 50 l/min	Different	
Degree of protection against dust and water	IP54 protection against the ingress of dust and splash water from all sides	IP 56	Different	The protection against contact and dust deposit is identical between the predicate and the subject device, but the protection against the ingress of water is higher for the predicate device since this device has no electrical components. Nevertheless, the minimum required protection class is fulfilled and the devices are considered substantially equivalent.

Summary of Peformance Testing

Biocompatibility

A biological evaluation was performed on the MEDUMAT Easy CPR that included several tests on the ISO 10993 and the ISO 18562 series of standards – for details please refer to the following table:

Test Item	Applied Standards	Standard Title	Test result
Cytotoxicity	ISO 10993-5:2009	Biological evaluation of medical devices—Part 5: Tests for in-vitro cytotoxicity	considered as “non-cytotoxic” to the sub-conlfuent monolayer of L-929 mouse fibro-plast cells
Sensitization	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irrita-tion and skin sensitization	polar and non-polar extracts of the test item were ‘‘non-sensitizer’’ to the skin of the guinea pigs under the experimental conditions employed.
Irritation	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irrita-tion and skin sensitization	polar and non—polar extracts of test item, were “non-irritant” to the skin of New Zea-land white rabbits under the experimental conditions and the dose employed as per the ISO 10993 Part 10:2010(E).
acute syste-mic toxicity	ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	no mortality or evidence of systemic tox-icity from the extracts injected into mice
Emissions of particulate matter	ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter	Therefore, it is concluded that exposures to particulates and VOCs, as released from the Medumat Easy CPR, are unlikely to re-sult in toxicological effects.
Emission of Volatile Or-ganic Com-pounds	ISO 18562-3:2017	Biocompatibi/ity evaluation of breathing gas pathways in healthcare applications - Part 3: Test for emission of volatile or-ganic compounds (VOCs)	

Test Item	Applied Standards	Standard Title	Test result
leachable	ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate	No organic compounds were identified in the WEINMANN patient valve tested for this study using the GC/MSD and ICP-MS extraction methods presented in this report.

EMC and electrical safety

Various tests regarding EMC and electrical safety were conducted according to IEC 60601-1 Edition 3.1 (2012) and series standards to verify the safety and effectiveness of the MEDUMAT Easy CPR. These include the following:

- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-8
- IEC 60601-1-12

As well as:

- AIM 7351731

Performance Testing

Several tests were conducted to verify the substantial equivalence between the MEDUMAT Easy CPR and the predicate device. Test reports show that MEDUMAT Easy CPR and the predicate device have the same ventilation mode characteristics. Furthermore, the test reports show that the performance of MEDUMAT Easy CPR is at least as good as the performance of the predicate device.

Test Item	Test result
Verification of technical data of MEDUMAT Easy CPR	Passed
Comparison of MMECPR and the predicate device Pneupac VR1 Standard: Characteristics of Demand Flow Mode: • inspiration trigger • expiration trigger • flow	Passed
Comparison of MMECPR and the predicate device Pneupac VR1 Standard: • ventilation mode characteristics (IPPV) • ventilation mode characteristics (manual Mode)	Passed
Comparison of MMECPR and the predicate device Pneupac VR1 Standard: • pressure limits	Passed

Test Item	Test result
Endurance and functional test of pressure relief valve / safety valve of MEDUMAT Esy CPR	Passed
The inspiratory and expiratory respiratory resistances of Smith Medical's Pneupac VR1 are determined and compared with those of the Medumat Easy CPR under different operating conditions.	Passed

Conclusion

Based on the validation testing performed and the information provided, the subject device MEDUMAT Easy CPR is substantially equivalent to the declared predicate.