September 13, 2019

Imtmedical AG
Colleen Watson
Director, Regulatory Affairs
26125 N. Riverwoods Blvd.
Mettawa, IL 60045
USA

Re: K183364
Trade/Device Name: bellavista 1000 and bellavista 1000e
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: August 13, 2019
Received: August 15, 2019

Dear Colleen Watson:

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,

James Lee
Assistant Director
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)*
K183364

Device Name

bellavista 1000 and bellavista 1000e

Indications for Use *(Describe)*

The bellavista 1000/1000e ventilator is intended to provide positive pressure ventilatory support to adult and pediatric patients and optionally infant and neonatal patients by qualified, trained personnel under the direction of a physician.

Environment of use: hospitals, sub-acute care facilities and intra-hospital transfer

When used on neonatal patients: The environment of use is the Neonatal Intensive Care Unit (NICU).

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

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92

The assigned 510(k) number is:

Submitted by:	imtmedical AG Gewerbestrasse 8 9470 Buchs SG Switzerland
Establishment Registration Number:	3004553423
Contact Person:	Colleen Watson Director, Regulatory Affairs Phone: (872) 757-0070 e-mail: colleen.okeeffe@vyaire.com
Date Summary Prepared:	August 12, 2019
Reason for Premarket Notification:	New Device
Trade Name:	bellavista 1000 and bellavista 1000e
Common/Usual Name:	Ventilator, continuous, facility use
Product Code:	CBK
Regulatory Class:	Class II
Predicate Device:	bellavista 1000 (K163127)

Reference devices:

Multiple reference devices have been used for the modifications to support substantial equivalence.

Manufacturer / Tradename	510(k) Number	Product Code
Hamilton C3	K161450	CBK, DQA
Dräger V500	K093633	CBK
CareFusion Avea	K103211	CBK
Pulmonetic Systems Palmtop Ventilator PTV-10	K070594	CBK
Vyaire SiPAP	K031745	CBK
Maquet Servo-u	K151814	CBK
Puritan Bennett 840	K151252	CBK

Device Description:

bellavista is an electronically controlled pneumatic ventilation system. It is powered by AC or DC and also provided with an internal battery. The bellavista pneumatic system supplies respiratory gas whilst the electrical systems control the pneumatics and provides the power supply.

The user can enter values or parameters in the bellavista via the touch screen. These inputs entail instructions for bellavista's pneumatic system to ventilate the patient with a precisely controlled gas mixture. bellavista gathers readings from the proximal flow sensor and other sensors within the ventilator.

Indications for Use:

The bellavista 1000/1000e ventilator is intended to provide positive pressure ventilatory support to adult and pediatric patients and optionally infant and neonatal patients by qualified, trained personnel under the direction of a physician.

Environment of use: hospitals, sub-acute care facilities and intra-hospital transfer

When used on neonatal patients: The environment of use is the Neonatal Intensive Care Unit (NICU).

Comparison of bellavista 1000/1000e to the predicate:

We present in the following tables a comparison of the subject device compared to the predicate and reference devices.

Table 1: Comparison of Indications for Use

	Subject bellavista 1000 / bellavista 1000e	**Predicate bellavista 1000 (K163127)**	**Remarks, Substantial equivalence**
Product code	CBK	CBK	The same classification
Intended use	The bellavista 1000/1000e ventilator is intended to provide positive pressure ventilatory support to adult and pediatric patients and optionally infant and neonatal patients.	The bellavista 1000 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics (IBW greater than 6 kg).	Neonates are included in the intended patient population of the reference device Hamilton C3 (K161450)
Environment of use	Environment of use: hospitals, sub-acute care facilities and intra-hospital transfer When used on neonatal patients: the environment of use is the NICU	Environment of use: hospitals, sub-acute care facilities and intra-hospital transfer	Both devices are substantially equivalent for environment of use for adult and pediatric patient population. The environment of use for neonatal and infant patients is substantially equivalent to the environment of use of the reference device, Hamilton C3 (K161450).
Intended users	It is intended for use by qualified, trained personnel under the direction of a physician.	It is intended for use by qualified, trained personnel under the direction of a physician.	Both devices are substantially equivalent
Patient population	Adults, pediatrics, infants and neonates	Adults and pediatrics (IBW greater than 6 kg)	Neonates and infants are included in the intended patient population of the reference device Hamilton C3 (K161450)

Comparison of Technological Characteristics

We have added SpO2 and EtCO2 monitoring to the device.

Discussion of the Differences:

Indications for Use

Indications for use are to provide positive pressure ventilator support to adults, pediatrics and neonates.

Technology

The technology of a turbine based portable ventilator is identical to the predicate.

Environment of Use

The environment of use – hospital and intra-hospital transport is equal to the predicate.

Patient Population

- The patient population of adults and pediatrics is equal to the predicate.
- The patient population of neonates is similar to the reference device Hamilton C3 (K161450)

Ventilation Modes

Adult/Pediatric Ventilation Modes

Ventilation modes that are equivalent and not changed between subject and predicate device bellavista 1000 are:

The following ventilation modes have been cleared in the predicate device (K163127):

- CPAP
- PCV
- P-A/C
- PC-SIMV
- PSV
- S
- S/T
- T
- beLevel
- APRV
- VCV
- V-A/C
- VC-SIMV

The following modes were not available in the predicate device bellavista 1000 (K163127) but are part of the subject device. We have utilized reference devices where applicable.

Neonatal ventilation modes (modes in K163127 but not for neonates)

As neonatal ventilation had not been cleared in predicate device bellavista 1000 (K163127), all neonatal modes are compared to reference devices.

Summary of Ventilation Mode Comparison

Ventilation modes are either equivalent to the predicate – bellavista 1000 (K163127) or are similar to one of the reference devices as identified. We compared the ventilation modes which had similar features and their operating ranges as well as waveforms and they were found to be substantially equivalent.

Substantial Equivalence Conclusion

We have compared the subject device bellavista 1000/1000e to the predicate device bellavista 1000 and where needed provided reference devices. The testing performed has demonstrated that the bellavista can be found to be substantially equivalent.