Safe BVM Corporation
% Sara Toyloy
President
Fabrica Consulting, LLC
73 Lincoln Drive
Sausalito, California 94965

Re: K212905
Trade/Device Name: Sotair™ Device
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: July 14, 2022
Received: July 18, 2022

Dear Sara Toyloy:

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, Ph.D.
Assistant 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)*
K212905

Device Name
Sotair™ Device

Indications for Use *(Describe)*
The Sotair™ device is intended for use with a manual resuscitator with air-tight connections, in non-breathing patients that require flow controlled ventilation using ambient air or a supplemental oxygen source. The Sotair device is a single use, disposable device added to a manual resuscitator and can be used for in-hospital, emergency, and transport care. The adult Sotair device comprises a flow-limiting valve that limits the inspiratory flow enabling providers to ventilate approximately 55 liters-per-minute (LPM). The flow-limiting valve is intended to minimize gastric inflation during manual ventilation. The Sotair device can be disabled by removing the device, thereby returning the manual resuscitator to its conventional operation. The Sotair device is intended for adult use only.

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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5. 510(k) Summary

1. **Submitter:** SafeBVM, Corporation

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   Date Prepared: August 17, 2022

2. **Device:**
   Proprietary Name: Sotair™ Device
   Common Name: Flow-Limiting Valve
   Regulation: 21 CFR § 868.5915
   Classification: Manual emergency ventilator
   Device Class: Class 2
   Device Code: BTM
   Review Panel: Anesthesiology

3. **Predicate Device:**

   Smart Bag *MO* (K021328), O-Two Systems International, Inc.
   No reference devices were used in this submission

4. **Device Description:**

The Sotair™ device is a universal safety accessory device that is compatible with all manual resuscitators and airway interfaces that have standard ISO 5356-1:2015 15/22 mm connections. The Sotair device's flow-limiting function has been tested with the following bag resuscitators:

Model Number	Description/Brand Name	Manufacturer
520 211 00X, 520 211 00XX	Ambu Spur II, adult	Ambu
2442-BVMPAD	Curaplex Resuscitation Bags, adult premium BVM	Curaplex

Model Number	Description/Brand Name	Manufacturer
301-558XEA	Curaplex® VentiSure2™ BVM Manual Resuscitator, Adult	Curaplex
04-2K80XX	AirLife Adult Manual Resuscitator	Vyaire Medical/Carefusion
AF5140MBX, AF5140MBXX	Sunmed/ventlab AirFlow Standard, Size 5	Sunmed/Ventlab
10564XX, 10585XX	Mercury Medical CPR 2 – Small Adult Bag	Mercury Medical
1056XXX. 10582XX	Adult CPR-2 Bag	Mercury Medical
850XX	1st Response Adult Manual Resuscitator with Oxygen Reservoir Bag	Smith's Medical
8451X1	The BAG II Resuscitator Adult w/ Mask #5	Laerdal
562013	Adult BagEasy Resuscitator w/ Mask	Westmed
L670-0X0XX	Disposable Bag Mask Resuscitator	Allied Healthcare Products
53710X	RUSCH, Manual Pulmonary Resuscitator with oxygen reservoir bag, Adult	Teleflex

The Sotair device is not compatible with manual resuscitators that have a built-in flow limiting device.

5. Indications for Use:

The Sotair device is intended for use with a manual resuscitator with air-tight connections, in non-breathing patients that require flow-controlled ventilation using ambient air or a supplemental oxygen source. The Sotair device is a single use, disposable device added to a manual resuscitator and can be used for in-hospital, emergency, and transport care. The adult Sotair device comprises a flow-limiting valve that limits the inspiratory flow enabling user to ventilate approximately 55 liters-per-minute (LPM). The flow-limiting valve is intended to minimize gastric inflation during manual ventilation. The Sotair device can be disabled by removing the device, thereby returning the manual resuscitator to its conventional operation. The Sotair device is for adult use only.

6. Comparison of Indications for Use and Technological Characteristics with the Predicate Device:

Comparison of Indications for Use:
The Sotair device is a flow-limiting valve with the primary function of minimizing gastric inflation during manual ventilation. This intended use statement is the same as the predicate device with regard to the Smart Bag *MO*'s flow-limiting-valve which provides the same primary function of minimizing gastric inflation during manual ventilation. Small differences exist between the two intended uses wherein the Sotair device has a statement indicating that "the device is intended for

use in conjunction with a manual resuscitator which does not have a flow-limiting valve" whereas the predicate Smart Bag *MO* indicates that "the Smart Bag *MO* includes a flow-limiting valve that limits the inspiratory flow". Additional differences exist between the two devices including the maximum ventilation rate of ~55 LPM and the targeted patient population (adult use only) for Sotair, however, these differences do not impact the substantial equivalence of the Sotair device as compared to the predicate device.

Comparison of Technological Characteristics:
The Sotair device (subject device) differs from the predicate device with regard to the actual mechanism that is used to limit the flow rate. Specifically, the Sotair device uses a flapper valve with a blade design whereas the Smart Bag *MO* (predicate device) uses a t-shaped piston with spring design. While the actual morphology differs between the two devices, the mechanism of action is the same for both devices, i.e., the flow-limiting valve becomes activated when the provider squeezes the bag forcefully (i.e., too hard). The Sotair device and the Smart Bag *MO* mechanisms are both actuated with excessive force and enable the provider to limit inspiratory flows delivered to the patient. When activated, the flow-limiting valve mechanisms of both devices move within their respective housing to limit flow. Both valves are brightly colored to aid in visualization, and their plastic components consist of similar medical-grade polycarbonate material.

7. Performance Data:

To demonstrate that the differences in technological characteristics specific to the flow-limiting valve mechanism do not impact the substantial equivalence of the Sotair device (subject device) to the Smart Bag *MO* device (predicate device), performance testing was completed to support the determination of substantial equivalence as follows:

Biocompatibility Testing:

Biological safety testing on the final, finished Sotair device was conducted in accordance with ISO 10993 and ISO 18562. The Sotair device has contact with the humidified breathing gas pathway for a limited duration (<24 hours) according to ISO 10993-1 and ISO 18562-1. While the actual clinical use is typically brief, under extreme conditions, the device could be used for up to 6 hours. The Sotair device was evaluated for the following endpoints through testing: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Material-mediated Pyrogenicity, Volatile Organic Compound (VOC) emissions, Particulates, and Leachable Substances in condensate *via* ISO 10993-18. Toxicological Risk Assessments were conducted according to ISO 10993-17 and ISO 18562-1. Overall, the testing met the requirements of ISO 10993 and ISO 18562.

Mechanical Testing:

The following mechanical tests were completed at Time Zero and Time 2-years (accelerated) to support the substantial equivalence determination:

- Auditory Feedback, Bounce Back and Valve Penetration Testing
- Forward and Backward Air Leakage and Expiratory and Inspiratory Resistance Testing

- Drop Testing
- Water Immersion Testing
- Valve Functionality Testing
- Bag Valve Connectors*
- Maximum Threshold Testing
- Dead Space Testing*
- Shelf Life Testing (comprised of the applicable the mechanical testing described above)
- Resuscitator Compatibility Testing
- Accessory Compatibility Testing

*Time Zero testing only.

The Sotair device performance testing considered the applicable sections of the following two standards where appropriate:

- ISO 5356-1:2015 – Anaesthetic and respiratory equipment – conical connectors – Part 1: Cones and sockets.
- ISO 10651-4:2002 - Lung ventilators Part 4: Particular requirements for operator-powered resuscitators.

Device Risk Assessment:

The Sotair device risk assessment was conducted in accordance with ISO 14971 Medical Devices – Application of Risk management to Medical Devices.

Human Factors / Usability Testing:

SafeBVM conducted a simulated-use Human Factors Engineering / Usability Engineering (HFE/UE) Summative / Validation Study (summative study) on the Sotair device. This study was conducted in accordance with the Guidance for Industry and Food and Drug Administration Staff – Applying Human Factors and Usability Engineering to Medical Devices; February 3rd, 2016. The study concluded that the Sotair device met the criteria for use with the intended users, uses, and use environments. The overall result of the Usability Studies confirm that the Sotair device is designed, functions and meets the expectations and need for use.

8. Conclusions:

The performance data demonstrated that the Sotair device met the product specifications and also performed equivalent to the predicate device in the Valve Functionality Testing which included direct comparison to the Smart Bag *MO*. The simulated-use Human Factors Engineering / Usability Engineering (HFE/UE) Summative / Validation Study (summative study) demonstrated that the critical tasks and severity level were considered acceptable with the analysis of users, uses and use environments. Overall, this data demonstrates that the Sotair device (subject device) is substantially equivalent to the Smart Bag MO (predicate device).