April 25, 2025

Compact Medical, Inc.
% Allison Komiyama
VP, Medtech Innovations
Rqm+
2790 Mosside Blvd.
Suite 800
Monroeville, Pennsylvania 15146

Re: K243861
Trade/Device Name: butterflyBVM
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: December 12, 2024
Received: December 16, 2024

Dear Allison Komiyama:

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,

John S. Bender -S
2025.04.25 15:14:01 -04'00'

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243861

Device Name

butterflyBVM™

Indications for Use *(Describe)*

The butterflyBVM™ when used in transport and non-clinical emergency settings (e.g., EMS, non-hospital) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, infants, and neonates.

The butterflyBVM™ when used in professional healthcare facilities (e.g., hospitals) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, and infants.

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
K243861

DATE PREPARED
April 25, 2025

MANUFACTURER AND 510(k) OWNER
Compact Medical
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jgutermuth@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	butterflyBVM™
Common Name:	Manual Emergency Ventilator
Regulation Number:	21 CFR 868.5915
Class:	II
Product Code:	BTM
Premarket Review:	Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C)
Review Panel:	Anesthesiology

PREDICATE DEVICE IDENTIFICATION
The butterflyBVM™ is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K152931	Spur II/Ambu	✓

DEVICE DESCRIPTION
The butterflyBVM™ is a three-in-one bag-valve-mask capable of resuscitating adults, adolescents, children, infants, and neonates. The maximum tidal volumes (Vt) delivered by the butterflyBVM™ can be set via the tidal volume dial, as needed, to ranges that are generally appropriate for the size of patient receiving care. The butterflyBVM™ also has an adjustable peak inspiratory pressure (PIP) dial to help prevent barotrauma. The tidal volume and PIP are

selected by aligning the dials to the Vt/PIP indicator. Patient-facing accessories such as masks, laryngeal mask airways, endotracheal tubes, end-tidal CO_2 samplers, and the like can be connected to the patient connection port. Exhalation accessories such as bio filters and PEEP valves can be connected to the exhalation port. Supplemental oxygen can be added via the oxygen inlet port. The device is operated by manually squeezing the side arms together with either one or two hands. A cover is provided over the PIP dial to provide instruction to the user via images and words to first set the tidal volume for the procedure based on the assessment of the patient.

INDICATIONS FOR USE

The butterflyBVM™ when used in transport and non-clinical emergency settings (e.g., EMS, non-hospital) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, infants, and neonates.

The butterflyBVM™ when used in professional healthcare facilities (e.g., hospitals) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, and infants.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Compact Medical believes that the butterflyBVM™ is substantially equivalent to the predicate devices based on the information summarized here:

	Subject Device	***Predicate Device***	
	Compact Medical ButterflyBVM™ K243861	Ambu, Inc. Spur II K152931	Substantial Equivalence Discussion
Device Image			
Indications for Use	The butterflyBVM™ when used in transport and non-clinical emergency settings (e.g., EMS, non-hospital) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, infants, and neonates. The butterflyBVM™ when used in professional healthcare facilities (e.g., hospitals) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, and infants.	The Ambu SPUR II resuscitator is a single patient use resuscitator intended for pulmonary resuscitation. The range of the application for each version is: Adult: Adults and children with a body weight more than 30kg (66lb). Pediatric: Infant and children with a body weight up to 30kg (66lb). Infant: Neonates and infant with a body weight up to 10kg (22lb).	Similar. The subject device is offered in a single configuration which is manipulated for each patient while the predicate device comes in three sizes for each population. Both devices are intended to be used on the same spread of patient populations.
Product Codes / Regulation Number	BTM / 21 CFR 868.5915	BTM / 21 CFR 868.5915	Same
Regulation Description	Manual Emergency Ventilator	Manual Emergency Ventilator	Same

	Subject Device	***Predicate Device***	
	Compact Medical ButterflyBVM™ K243861	Ambu, Inc. Spur II K152931	Substantial Equivalence Discussion
Patient Population	Adults, adolescents, children, infants, and neonates.	Adults, adolescents, children, infants, and neonates.	Same
Environment of Use	Professional healthcare facilities and transport environments.	Professional healthcare facilities and transport environments.	Same
Single Patient Use	Single patient use	Single patient use	Same
Sterilization	Non-sterile	Non-sterile	Same
Prescription	Rx Only	Rx Only	Same
Magnetic Resonance Compatibility	MR Conditional	MR Conditional	Same
Performance Standards Utilized	• ISO 10651-4 *Lung ventilators Part 4: Particular requirements for user-powered resuscitators* • ISO 5356-1 *Anaesthetic and respiratory equipment — Conical connectors*	• ISO 10651-4 *Lung ventilators Part 4: Particular requirements for user-powered resuscitators* • ISO 5356-1 *Anaesthetic and respiratory equipment — Conical connectors*	Same

	Subject Device	***Predicate Device***	
	Compact Medical ButterflyBVM™ K243861	Ambu, Inc. Spur II K152931	Substantial Equivalence Discussion
Biocompatibility	• ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* • ISO 10993-10 *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization* • ISO 10993-11 *Biological evaluation of medical devices – Part 11: Test for systems toxicity* • ISO 10993-23 *Biological evaluation of medical devices - Part 23: Tests for irritation* • ISO 18562-1 *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process* • ISO 18562-2 *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter* • ISO 18562-3 *Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 3: Tests for emissions of volatile organic compounds* • ISO 18562-4 *Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 4: Tests for leachables in condensate*	• ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* • ISO 10993-10 *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*	Similar. The subject device has been evaluated to demonstrate biocompatibility to more endpoints than the predicate.
Shelf Life	• 6 months	• Not stated	Similar. Difference in shelf life does not raise questions of safety or effectiveness.

	Subject Device	***Predicate Device***	
	Compact Medical ButterflyBVM™ K243861	Ambu, Inc. Spur II K152931	Substantial Equivalence Discussion
Principles of Operation	A manual emergency bag-valve-mask ventilator incorporating a bellows and valve, intended to provide emergency respiratory support to a patient's airway. A single device design is adjustable for each patient population.	A manual emergency bag-valve-mask ventilator incorporating a bag and valve, intended to provide emergency respiratory support to a patient's airway. Three sizes of device are available for three different patient populations.	Similar. The subject device is offered in a single configuration and is manipulated to be used on all intended patient populations while the predicate is provided in three separate sizes.
Pressure Limiting Valve (PIP)	Default: 40cmH2O Max: No pressure limiting (override) In a study of the butterflyBVM versus the Ambu Spur II [Merrell et al. 2023], the use of the PIP Dial on the butterflyBVM was tested against the Ambu Disposable Pressure Manometer in achieving certain target pressures. The default pressure mechanisms for each device were tested. Results: Target Max PIP: 40cmH2O butterflyBVM: 0 failures with 40cmH2O max PIP delivered	Infant and Pediatric: Default: 40cmH20 Max: No pressure limiting (override) Adult: Default: No pressure limiting (override) Results: Target Max PIP: 40cmH2O Ambu Spur II: 21 failures with 44.0cmH2O max PIP delivered	Similar. The subject device features a PIP dial rather than a pop-off valve. The subject device has the ability to be set to a lower minimum pressure; however, the default settings and override capability are the same between the subject and predicate, and the subject has demonstrated superiority to the predicate in venting pressures above the default setting.

	Subject Device	***Predicate Device***	
	Compact Medical ButterflyBVM™ K243861	Ambu, Inc. Spur II K152931	Substantial Equivalence Discussion
Delivered Volume One Hand	Min: 30 ml Max: 565 ml	Min (smallest size device): 150 ml Max (largest size device): 600 ml	Similar. The subject device is capable of delivering a smaller minimum value than the smallest size of the predicate.
Delivered Volume Two Hands	Min: 70 ml Max: 715 ml	Min (smallest size device): not reported Max (largest size device): 1000 ml	Similar. The predicate device does not state a two-hand delivered volume for the smallest device. The maximum volumes are similar.
Operating Temperature	-18°C to +50°C	-18°C to +50°C	Same
Storage Conditions	-40°C to +60°C	- 40 °C to + 60 °C	Same

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th></th></tr>
<tr><td></td><td>Compact Medical

ButterflyBVM™
K243861</td><td>Ambu, Inc.

Spur II
K152931</td><td>Substantial Equivalence Discussion</td></tr>
<tr><td>Delivered Oxygen Concentration</td><td>
<table>
<tr><th rowspan="2">Setting</th><th rowspan="2">Inspiratory Rate (BPM)</th><th rowspan="2">Stroke Volume* (ml)</th><th colspan="3">Nominal Oxygen Concentration (%) at a Given O_2 Flow Rate</th></tr>
<tr><th>5 LPM</th><th>10 LPM</th><th>15 LPM</th></tr>
<tr><td>Adult Large</td><td>10</td><td>565</td><td>61</td><td>78</td><td>90</td></tr>
<tr><td>Adult Med</td><td>10</td><td>510</td><td>62</td><td>79</td><td>91</td></tr>
<tr><td>Adult Small</td><td>10</td><td>415</td><td>66</td><td>83</td><td>93</td></tr>
<tr><td>10-13 YRS</td><td>20</td><td>380</td><td>62</td><td>79</td><td>90</td></tr>
<tr><td>7-9 YRS</td><td>20</td><td>275</td><td>72</td><td>87</td><td>95</td></tr>
<tr><td>5-6 YRS</td><td>20</td><td>225</td><td>76</td><td>90</td><td>97</td></tr>
<tr><td>3-4 YRS</td><td>20</td><td>185</td><td>81</td><td>93</td><td>99</td></tr>
<tr><td>1-24 MOS</td><td>20</td><td>150</td><td>83</td><td>95</td><td>99</td></tr>
<tr><td>NEO</td><td>30</td><td>30</td><td>93</td><td>100</td><td>100</td></tr>
</table>
Table 2: Expected oxygen concentration at a given O_2 flow rate, inspiratory rate, and stroke volume. *Tested according to EN ISO 10651-4.
</td><td>
<table>
<tr><th>ADULT > 30 kg</th><th colspan="4">VT (ml) x f (pr. min.), I:E ratio = 1:2</th></tr>
<tr><td>O_2 (l/min)</td><td>250 x 12</td><td>600 x 12</td><td>750 x 12</td><td>1000 x 12</td></tr>
<tr><td>2</td><td>74</td><td>43</td><td>38</td><td>34</td></tr>
<tr><td>5</td><td>100</td><td>76</td><td>65</td><td>54</td></tr>
<tr><td>10</td><td>100</td><td>100</td><td>100</td><td>87</td></tr>
<tr><td>15</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
</table>
<table>
<tr><th>PEDIATRIC 6 - 30 kg</th><th colspan="4">VT (ml) x f (pr. min.), I:E ratio = 1:2</th></tr>
<tr><td>O_2 (l/min)</td><td>40 x 40</td><td>100 x 20</td><td>200 x 20</td><td>400 x 15</td></tr>
<tr><td>1</td><td>70</td><td>60</td><td>40</td><td>34</td></tr>
<tr><td>2</td><td>100</td><td>100</td><td>60</td><td>47</td></tr>
<tr><td>4</td><td>100</td><td>100</td><td>100</td><td>73</td></tr>
<tr><td>6</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
</table>
<table>
<tr><th>INFANT < 10 kg</th><th colspan="6">VT (ml) x f (pr. min.), I:E ratio = 1:1</th></tr>
<tr><td rowspan="2">O_2 (l/min)</td><td colspan="2">40 x 40</td><td colspan="2">100 x 20</td><td colspan="2">150 x 20</td></tr>
<tr><td>Reservoir Bag</td><td>10" Tube</td><td>Reservoir Bag</td><td>10" Tube</td><td>Reservoir Bag</td><td>10" Tube</td></tr>
<tr><td>1</td><td>70</td><td>70</td><td>60</td><td>60</td><td>47</td><td>47</td></tr>
<tr><td>2</td><td>100</td><td>100</td><td>100</td><td>100</td><td>73</td><td>73</td></tr>
<tr><td>4</td><td>100</td><td>100</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>6</td><td>100</td><td>100</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
</table>
Calculated delivered O_2 %*
</td><td>Similar. The predicate provides calculated percentages while the subject device has demonstrated nominal oxygen concentrations at given flow rates through actual testing per EN ISO 10651-4. Both data sets meet the consensus standard requirement of ≥85% FiO2 at a flow rate of 15 LPM</td></tr>
</table>

	Subject Device	***Predicate Device***	
	Compact Medical ButterflyBVM™ K243861	Ambu, Inc. Spur II K152931	Substantial Equivalence Discussion
Comparative Testing	butterflyBVM PIP Dial In a study of the butterflyBVM versus the Ambu Spur II [Merrell et al. 2023], the use of the PIP Dial on the butterflyBVM was tested against the Ambu Disposable Pressure Manometer in achieving certain target pressures. Results: Target Max PIP: ≤20cmH2O butterflyBVM: 1 failure with 20.3cmH2O max PIP delivered Target Max PIP: ≤30cmH2O butterflyBVM: 1 failure with 30.4cmH2O max PIP delivered	Ambu Disposable Pressure Manometer On Ambu Spur II pediatric and infant devices, the default pop off value is 40cmH2O. Results: Target Max PIP: ≤20cmH2O Ambu Spur II: 23 failures with 23.7cmH2O max PIP delivered Target Max PIP: ≤30cmH2O Ambu Spur II: 32 failures with 37.9cmH2O max PIP delivered	Similar. The Ambu Spur II Disposable Pressure Manometer is capable of measuring pressures between 5 and 60cmH2O whereas the butterflyBVM is capable of restricting the pressures between 15 and 60cmH2O. Comparative testing demonstrates that the butterflyBVM showcases repeatability and precision in achieving target pressures thereby demonstrating substantial equivalence.

The butterflyBVM™ and the Spur II have the same intended use and similar indications, technological characteristics and similar principles of operation. The main technological differences between the subject device and its predicate are the design of the bellows, the variable tidal volume dial, the adjustable peak inspiratory pressure dial, and biocompatibility endpoints. The gas pathway of the subject device has been evaluated per the ISO 18562 series of standards. The minor differences do not present any new issues of safety or effectiveness because the materials of the subject device have passed biocompatibility testing according to rigorous endpoints and the bench testing has shown that despite design differences, the devices perform comparably and according to recognized consensus standards. Thus, the butterflyBVM™ is substantially equivalent to the Spur II.

SUMMARY OF NON-CLINICAL TESTING

FDA-recognized performance standards have been established for the butterflyBVM™. The following tests were performed to demonstrate safety based on current industry standards:

• ISO 10651-4 *Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators*

• ISO 5356-1 *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

Result: All tests passed.

Connectors

- Patient connection port connector
- Expiratory port connector for breathing gases
- Oxygen tube connector

Operation requirements

- Patient valve function after contamination with vomitus
- Mechanical strength /Drop test
- Immersion in water
- Minimum number of cycles

Ventilatory requirements

- Supplementary oxygen and delivered oxygen concentration
- Expiratory resistance
- Inspiratory resistance
- Patient valve malfunction
- Resuscitator deadspace and rebreathing

Ventilation performance

- Minimum delivered volume
- Pressure limitation

Storage and Operation

- Inspiratory/Expiratory resistance test
- Stroke volume test
- Patient valve malfunction test
- Supplementary oxygen and delivery oxygen concentration
- Pressure limitation test

The results of these tests indicate that the butterflyBVM™ is substantially equivalent to the predicate device.

CONCLUSION

Based on the testing, including performance testing per recognized consensus standards and biocompatibility, it can be concluded that the subject device does not raise new questions of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed butterflyBVM™ are assessed to be substantially equivalent to the predicate device.