November 24, 2025

Laerdal Medical AS
% Daniel Dillon
Senior Regulatory Scientist
MED Institute
1330 Win Hentschel Boulevard
Suite 100
West Lafayette, Indiana 47906

Re: K251631
Trade/Device Name: The BAG manual resuscitator and accessories
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: Class II
Product Code: BTM, BYE, CAP
Dated: May 27, 2025
Received: May 28, 2025

Dear Daniel Dillon:

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

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.

Submission Number *(if known)*

K251631

Device Name

The BAG manual resuscitator and accessories

Indications for Use *(Describe)*

The BAG is indicated for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen. The BAG is intended to be used in both pre-hospital and healthcare facility environments.

The sizes versions also include indications for the patient population:

Adult: The Adult model is intended for patients over 20 kg (44 lbs).
Pediatric: The Pediatric model is intended for patients 2.5 - 20 kg (5.5 - 44 lbs).
Newborn: The Newborn model is intended for patients 2.5 - 5 kg (5.5 -11 lbs).

The BAG PEEP Valve is indicated for patients in need of ventilatory support with positive end-expiratory pressure (PEEP). The BAG PEEP valves can be used for all patient sizes indicated for The BAG manual resuscitator. The BAG PEEP valve is intended to be used in both pre-hospital and healthcare facility environments.

The BAG Manometer is indicated for measuring the gas pressure provided to a patient requiring total or intermittent ventilatory support. The BAG Manometer can be used for all patient sizes indicated for The BAG manual resuscitator. The BAG Manometer is intended to be used in both pre-hospital and healthcare facility environments.

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

The BAG manual resuscitator
21 CFR 868.5915
Date Prepared: November 20, 2025

Submitted By Claudia Pajares Ibanez, Manager, Regulatory Affairs
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Device Information

The BAG manual resuscitator and accessories have the following names and classifications:

Trade Name	Common Name	Classification Name	Regulation	Class	Product Code
The BAG	manual resuscitator	Manual emergency ventilator	868.5915	II	BTM
The BAG	PEEP valve	Positive end expiratory pressure breathing attachment	868.5965	II	BYE
The BAG	Manometer	Airway pressure monitor	868.2600	II	CAP

Indications for Use

The BAG is indicated for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen. The BAG is intended to be used in both pre-hospital and healthcare facility environments.

The sizes versions also include indications for the patient population:

Adult: The Adult model is intended for patients over 20 kg (44 lbs).
Pediatric: The Pediatric model is intended for patients 2.5 - 20 kg (5.5 - 44 lbs).
Newborn: The Newborn model is intended for patients 2.5 - 5 kg (5.5 -11 lbs).

The BAG PEEP Valve is indicated for patients in need of ventilatory support with positive end-expiratory pressure (PEEP). The BAG PEEP valves can be used for all patient sizes indicated for The BAG manual resuscitator. The BAG PEEP valve is intended to be used in both pre-hospital and healthcare facility environments.

The BAG Manometer is indicated for measuring the gas pressure provided to the patient requiring total or intermittent ventilatory support. The BAG Manometer can be used for all patient sizes indicated for The BAG manual resuscitator. The BAG Manometer is intended to be used in both pre-hospital and healthcare facility environments.

Predicate Devices

The BAG manual resuscitator is substantially equivalent to the Flexicare Single Use Resuscitator Bag (510(k) No. K181583, cleared December 7, 2018).

The BAG PEEP Valve is substantially equivalent to the PEEP valve described in the 510(k) for the Hsiner Resuscitator and PEEP Valve (510(k) No. K053466, cleared March 22, 2006).

The BAG Manometer is substantially equivalent to the Intersurgical 7160030 Manometer (510(k) No. K122077, cleared January 10, 2013).

Device Description

The BAG is a non-sterile self-inflating manual resuscitator. It is indicated for patients requiring ventilatory support. Ventilation is possible with or without supplemental oxygen. The BAG manual resuscitator is intended for short-term use (< 24 hours per patient) and may be used multiple times on a single patient when kept free from contamination. It is available in three sizes: adult (for patients > 20 kg (44 lbs.)), pediatric (for patients 2.5-20 kg (5.5-44 lbs.)), and newborn (for patients 2.5-5 kg (5.5-11 lbs.)).

The BAG PEEP Valve is a non-sterile single patient use PEEP Valve, for use with The BAG manual resuscitator to maintain positive end expiratory pressure (PEEP). It is indicated for patients in need of ventilatory support with PEEP. It may be used multiple times on a single patient when kept free from contamination. The device has four parts: a main body, an adjustable screw cap, inner valve, and one or two springs (one for the 2-10 cmH_2O version and two for the 5-20 cmH_2O version). It attaches to the expiratory port of The BAG manual resuscitator. The BAG PEEP valve comes in two versions, one with a range of 2-10 cmH_2O and one with a range of 5-20 cmH_2O. The 2-10 cmH_2O version has a stated accuracy of +1/-2 cmH_2O at 2 cmH_2O and a stated accuracy of +1/-3 cmH_2O at 5-10 cmH_2O. The 5-20 cmH_2O version has a stated accuracy of ±3 cmH_2O throughout its range.

The BAG Manometer is a non-sterile single patient use airway pressure manometer, for use with The BAG manual resuscitator. The BAG Manometer is indicated for measuring the gas pressure provided to the patient. It provides a visual indication of gas pressure provided to the patient. It is intended for short-term use (< 24 hours per patient) and may be used multiple times on a single patient when kept free from contamination. The device has a range of 0-60 cmH_20 and is accurate to ±10% of the reading in the range of 20-60 cmH_20.

The use of either of the two accessories is optional, i.e., they are used at the discretion of the healthcare professional.

Substantial Equivalence

The three tables below present the similarities and differences between the submitted devices and the predicate devices for substantial equivalence purposes. The differences between the submitted devices and the predicate devices do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence and were developed using acceptable scientific methods for evaluation.

Table 1 Comparison of The BAG manual resuscitator to the Flexicare Single Use Resuscitator Bag

<table>
<tr><th></th><th>The BAG manual resuscitator
(Subject of this submission)</th><th>Flexicare Single Use Resuscitator Bag
(K181583)</th><th>Comparison</th></tr>
<tr><td>General</td><td></td><td></td><td></td></tr>
<tr><td>Intended use</td><td>Provides emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.</td><td>Provides emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.</td><td>Same</td></tr>
<tr><td>Indications for use</td><td>Device is available in three sizes, each having slightly different indications for use statements, that follows this template:
“The BAG is indicated for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen. The [X] model is intended for patients [Y]. The BAG is intended to be used in both pre-hospital and healthcare facility environments.”
The variable text is as follows:<table><tr><th>[X]</th><th>[Z]</th></tr><tr><td>Adult</td><td>over 20 kg
(44 lbs)</td></tr><tr><td>Pediatric</td><td>2.5 - 20 kg
(5.5 - 44 lbs).</td></tr><tr><td>Newborn</td><td>2.5 - 5 kg
(5.5 -11 lbs)</td></tr></table></td><td>Device is available in three sizes, each having slightly different indications for use statements, that follows this template:
“Flexicare’s [X] Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of [Y] with a body weight of [Z]. For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and pre-hospital environments.”
The variable text is as follows:<table><tr><th>[X]</th><th>[Y]</th><th>[Z]</th></tr><tr><td>Adult</td><td>adult patients</td><td>more than 66 lbs.
(30 kg)</td></tr><tr><td>Pediatric</td><td>infants and children</td><td>22 lbs. to 66 lbs.
(10-30 kg)</td></tr><tr><td>Infant</td><td>neonates and infants</td><td>up to 22 lbs.
(10 kg)</td></tr></table></td><td>Equivalent. Indications for use can vary, yet substantial equivalence is supported, because the two devices have the same intended use.
Based on the range of sizes, the devices have nearly identical patient populations. Size version of the resuscitators cover the ventilatory performance patient body mass ranges of ISO 10651-4:2002. The lower end for The BAG manual resuscitator is 2.5 kg (5.5 lbs), while the predicate device indicates no lower weight range. Thus, The BAG manual resuscitator’s patient population is within the range of the predicate’s patient population.</td></tr>
<tr><td>Prescription status</td><td>Prescription use only</td><td>Prescription use only</td><td>Same</td></tr>
</table>

	The BAG manual resuscitator (Subject of this submission)	Flexicare Single Use Resuscitator Bag (K181583)	Comparison
Environment of use	Healthcare facilities, pre-hospital	Hospital, pre-hospital	Equivalent. "Healthcare facilities" is slightly broader than "hospital", but is not a significant change with respect to substantial equivalence because, regardless of the environment of use, both devices are intended to be used by healthcare professionals trained in resuscitation, delivering ventilatory support and in the use of manual resuscitators.
Intended users	Healthcare professionals trained in resuscitation, delivering ventilatory support and in the use of manual resuscitators.	CPR-trained personnel only	Same. The term "health care professionals trained in resuscitation" refers to individuals certified in CPR. Thus, although the wording is different, the intended users are the same.
Design			
Principle of operation	Manual inflation of lungs via bag with valves to allow addition of oxygen and prevention of rebreathing expired air.	Manual inflation of lungs via bag with valves to allow addition of oxygen and prevention of rebreathing expired air.	Same
Ventilation bag sizes Adult	1800 ml	Equivalent. Ventilation bag size is a design choice. The substantial equivalence of the sizes is demonstrated by performance testing to FDA-recognized consensus standards, most especially to ISO 10651-4.	Equivalent. Ventilation bag size is a design choice. The substantial equivalence of the sizes is demonstrated by performance testing to FDA-recognized consensus standards, most especially to ISO 10651-4.
Pediatric	588 ml	635 ml	
Newborn	318 ml	370 ml	
Key components	• Ventilation bag • Patient, inlet and pressure-relief valves • Oxygen reservoir • PEEP valve option • Manometer option	• Ventilation bag • Patient, inlet and pressure-relief valves • Oxygen reservoir • PEEP valve option • Manometer option • Medication port • CO_2 monitoring port • Face mask	Equivalent. The predicate device includes the same components as The BAG manual resuscitator, plus a few components that are optional, i.e., not critical to the safe and effective performance of the device. A medication port is not necessary because drug delivery can be performed (and is preferably performed) without passing through a resuscitator. A CO_2 monitoring port is not necessary because a T-adapter with gas sampling port can be attached to the device at the user's discretion. Note also that neither ISO 10651-4:2002 nor ISO 10651-4:2023 require manual resuscitators to include these two functions. Face masks are outside the scope of the submission. Thus, the differences do not impact substantial equivalence.

		The BAG manual resuscitator (Subject of this submission)	**Flexicare Single Use Resuscitator Bag (K181583)**	**Comparison**
Key materials		• Ventilation bag – TPE • Connectors – Polycarbonate and HDPE • Valves – Silicone • O_2 tubing – PVC • Reservoir bag – LDPE • Valve spring – Stainless steel	• Ventilation bag – TPE • Connectors – ABS • Valves – Silicone • O_2 Tubing – PVC • Reservoir bag – PVC • Valve spring – Stainless steel	Equivalent. The substantial equivalence of the devices with respect to material is supported by performance testing and biocompatibility evaluation using FDA-recognized consensus standards.
Compliance to FDA recognized standards		• ISO 10651-4:2002 • ISO 18562-1:2017 • ISO 18562-2:2017 • ISO 18562-3:2017 • ISO 18562-4:2017 • ISO 5356-1:2015	• EN ISO 10651-4:2009 (ISO 10651-4:2002) • BS ISO 18562-2 2017 • ISO 5356-1:2004	Equivalent. The BAG manual resuscitator uses the current versions of two FDA-recognized standards (ISO 10651-4 and ISO 5356-1) and additional FDA-recognized standards in the ISO 18562-series of standards. Thus, The BAG manual resuscitator supplies the same or a higher assurance of safety and effectiveness with respect to the scope of the standards, supporting substantial equivalence.
Reuse status		Single patient use, < 24 hours	Single use	Same, with clarification of length of use, which does not affect substantial equivalence.
Sterility status		Nonsterile	Nonsterile	Same.
Performance				
Inspiratory resistance	Adult	4.2 cmH_2O @ 50 L/min	1.5 cmH_2O @ 50 L/min	Equivalent. The ISO 10651-4:2002 requirement for inspiratory and expiratory resistance is < 5 cmH_2O, for (a) body mass ≤ 10 kg @ 5 l/min, and (b) body mass > 10 kg @ 50 l/min. Both devices meet this requirement, supporting substantial equivalence.
	Pediatric	4.0 cmH_2O @ 50 L/min and 0.5 cmH_2O @ 5 L/min	1.5 cmH_2O @ 50 L/min	
	Newborn	0.4 cmH_2O @ 5 L/min	0.4 cmH_2O @ 5 L/min	
Expiratory resistance	Adult	2.6 cmH_2O @ 50 L/min	1.7 cmH_2O @ 50 L/min	
	Pediatric	2.8 cmH_2O @ 50 L/min and 0.3 cmH_2O @ 5 L/min	1.7 cmH_2O @ 50 L/min	
	Newborn	0.4 cmH_2O @ 5 L/min	0.9 cmH_2O @ 5 L/min	
Deadspace volume	Adult	6.90 ml	4.27 ml	Equivalent. Although The BAG resuscitator exhibits a slightly higher deadspace volume compared to the predicate device, the values are within the requirements
	Pediatric	6.90 ml	5.01 ml	

		The BAG manual resuscitator (Subject of this submission)	**Flexicare Single Use Resuscitator Bag (K181583)**	**Comparison**
	Newborn	6.90 ml	4.46 ml	of ISO 10651-4:2002 (specifically, < 7 ml based on the minimum delivered volume). Thus, deadspace volume remains within clinically acceptable limits, does not raise new questions of safety or effectiveness this difference, and supports substantial equivalence.
Maximum limited pressure of pressure relief valve	Adult	60 ± 5 cmH_2O @ 60 L/min	Three versions: (1) 60 cmH_2O, (2) 40 cmH_2O, or (3) no pressure relief valve	Equivalent
	Pediatric	60 ± 5 cmH_2O @ 60 L/min; 41 ± 4 cmH_2O @ 15 L/min	40 cmH_2O	
	Newborn	41 ± 4 cmH_2O @ 15 L/min	40 cmH_2O	

Table 2 Comparison of The BAG PEEP Valve to the Hsiner PEEP valve

	The BAG PEEP Valve (Subject of this submission)	Hsiner PEEP Valve (K053466)	Comparison
General			
Intended use	Elevates pressure in a patient's lungs above atmospheric pressure at the end of exhalation.	Elevates pressure in a patient's lungs above atmospheric pressure at the end of exhalation.	Same
Indications for use	The BAG PEEP Valve is indicated for patients in need of ventilatory support with positive end-expiratory pressure (PEEP). The BAG PEEP valves can be used for all patient sizes indicated for The BAG manual resuscitator. The BAG PEEP valve is intended to be used in both pre-hospital and healthcare facility environments.	Used in conjunction with manual resuscitators and other ventilatory support equipment to provide positive end expiratory pressure.	Same (editorial differences only)
Prescription status	Prescription use only	Prescription use only	Same
Environment of use	Healthcare facilities, pre-hospital	Not stated	Equivalent. Based on the predicate device's indications for use, the environment of use is likely the same.
Intended users	Healthcare professionals trained in resuscitation, delivering ventilatory support with PEEP and in the use of manual resuscitators.	Not stated	Equivalent. Based on the predicate device's indications for use, the environment of use is likely the same.
Design			
Principle of operation	Adjustable spring-actuated valve	Adjustable spring-actuated valve	Same
Key components	• Valve • Spring • Housing	• Valve • Spring • Housing	Same key components
Key materials	• Valve – Silicone • Spring – Stainless steel • Housing – Polycarbonate	Not stated	Equivalent. Even though the materials of the predicate device are unknown, the substantial equivalence of the devices with respect to material is demonstrated by performance testing and biocompatibility evaluation using FDA-recognized consensus standards.
Reuse status	Single patient use, < 24 hours	Single use	Same, with clarification of length of use, which does not affect substantial equivalence.

	The BAG PEEP Valve (Subject of this submission)	**Hsiner PEEP Valve (K053466)**	**Comparison**
Sterility status	Nonsterile	Nonsterile	Same
Standards compliance	ISO 5356-1:2015	ISO 5356-1:2004	Equivalent. The BAG manual resuscitator uses the later version of the standard.
Performance			
PEEP pressure range	5-20 cmH_2O *or* 2-10 cmH_2O	5-20 cmH_2O *or* 2-10 cmH_2O	Same
Accuracy 5-20 cmH_2O	± 3 cmH_2O	Not stated	Equivalent. The 510(k) Summary of another device (Foremount Disposable PVC Resuscitator Model A1, A2, B1, B2 and Accessories, 510(k) K170663) has a similar pressure ranges (5-20 cmH_2O and 0-10 cmH_2O) and similar accuracy (± 2 cmH_2O). The differences in accuracy (in some cases 1 cmH_2O better, in other cases 1 cmH_2O worse) and not considered clinically significant and thus support substantial equivalence.
2-10 cmH_2O	+1/-2 cmH_2O @ 2 cmH_2O; +1/-3 cmH_2O @ 5-10 cmH_2O		

Table 3 Comparison of The BAG Manometer to the Intersurgical 7160030 Manometer

	The BAG Manometer (Subject of this submission)	Intersurgical 7160030 Manometer (K122077)	Comparison
General			
Intended use	Measures the pressure in a patient's upper airway.	Measures the pressure in a patient's upper airway.	Same
Indications for use	The BAG Manometer is indicated for measuring the gas pressure provided to the patient. The BAG Manometer can be used for all patient sizes indicated for The BAG manual resuscitator. The BAG Manometer is intended to be used in both pre-hospital and healthcare facility environments.	The Intersurgical In-line single patient use manometer is intended to be used for monitoring the patients airway pressure during ventilation. The manometer is to be used with resuscitation systems and Mapleson C breathing circuits.	Equivalent. Indications for use can vary, yet substantial equivalence is supported, because the two devices have the same intended use. The predicate device has a wider range of the use ("resuscitation systems"), but the fact that The BAG Manometer is used only with The BAG manual resuscitator does not create a new or different intended use.
Prescription status	Prescription use only	Prescription use only	Same
Environment of use	Healthcare facilities, pre-hospital	Hospital, ambulance, and all other environments	Equivalent. "Healthcare facilities" is slightly broader than "hospital", and The BAG Manometer is not intended for "all other environments" as was stated for the predicate device. These differences are not significant with respect to substantial equivalence because, regardless of the environment of use, both devices are intended to be used by healthcare professionals trained in resuscitation, delivering ventilatory support and in the use of manual resuscitators.
Intended users	Healthcare professionals trained in resuscitation, delivering ventilatory support and in the use of manual resuscitators.	Must only be used by personnel trained in resuscitation and/or airway resuscitation.	Equivalent. Although the predicate device uses different wording to describe intended users, the intender users are substantially the same.
Design			
Principle of operation	A balance of the force exerted by the air in the system and the force exerted by a calibrated spring defines the indicator position. The display on each manometer is a similar size and the pressure is specified where the indicator lines up with number marked on the outside of the transparent cylinder.	A balance of the force exerted by the air in the system and the force exerted by a calibrated spring defines the indicator position. The display on each manometer is a similar size and the pressure is specified where the indicator lines up with number marked on the outside of the transparent cylinder.	Same

	The BAG Manometer (Subject of this submission)	**Intersurgical 7160030 Manometer (K122077)**	**Comparison**
Key components	• Spring • Housing (i.e., cylinder) • Piston (i.e., indicator)	• Spring • Cylinder • Indicator	Same
Key materials	• Spring – Stainless steel • Housing – Polycarbonate • Exhaust port on housing - Silicone • Piston – Polycarbonate	• Steel • Polypropylene • Silicone • TPE • Styrene acrylonitrile resin	Equivalent. The substantial equivalence of the devices with respect to material is supported by performance testing and biocompatibility evaluation using FDA-recognized consensus standards.
Reuse status	Single patient use, < 24 hours	Single patient use	Same, with clarification of length of use, which does not affect substantial equivalence.
Sterility status	Nonsterile	Nonsterile	Same
Performance			
Pressure range	0-60 cmH_2O	0-60 cmH_2O	Same
Gradations	0-60 cmH_2O, in 10 cmH_2O increments	0-60 cmH_2O, in 10 cmH_2O increments	Same
Deadspace volume	< 7 ml (when combined with the resuscitator)	Unknown	The deadspace volume meets the requirements of ISO 10651-4:2002 for the operating environmental range, supporting substantial equivalence. The predicate does not provide this information in its labeling.
Measured Accuracy	±1 cmH_2O @ 10 cmH_2O ±2 cmH_2O @ 20 cmH_2O ±3 cmH_2O @ 30 cmH_2O ±4 cmH_2O @ 40 cmH_2O ±5 cmH_2O @ 50 cmH_2O ±6 cmH_2O @ 60 cmH_2O	±2 mbar (2 cmH_2O) @ 10 cmH_2O ±4 mbar (4 cmH_2O) @ 20 cmH_2O ±5 mbar (5 cmH_2O) @ 30 cmH_2O ±5 mbar (5 cmH_2O) @ 40 cmH_2O ±7 mbar (7 cmH_2O) @ 50 cmH_2O ±7 mbar (7 cmH_2O) @ 60 cmH_2O	Equivalent. The BAG Manometer is more accurate than the predicate device, supporting substantial equivalence. Note: Accuracy at 10 cmH_2O is not clinically significant. In the critical range of 40-60 cmH_2O, The BAG Manometer demonstrates better performance, supporting substantial equivalence.

Discussion of Tests and Test Results

Design verification and design validation testing demonstrates that The BAG manual resuscitator and accessories meet their functional requirements and performance specifications. In particular, testing was conducted on:

- The BAG manual resuscitator, in accordance with:
    - ISO 10651-4:2002, *Lung ventilators – Part* 4*: Particular requirements for operator-powered resuscitators,* using the resuscitator alone and with all accessories,
    - ISO 5356-1:2015, *Anesthetic and respiratory equipment – Conical connectors – Part* 1*: Cones and sockets.*
- The BAG manual resuscitator, for maximum deliverable tidal volume, dead space, and operation for 24 hours, in accordance with ISO 10651-4:2023, *Lung ventilators – Part* 4*: Particular requirements for operator-powered resuscitators.*
- The BAG PEEP Valve, for accuracy, using the operation and storage conditions and simulated ventilations from ISO 10651-4:2002.
- The BAG Manometer, for accuracy, using the operation and storage conditions from ISO 10651-4:2002.
- All accessories, for label durability and ability to withstand drops.
- All devices (separate and combined), for magnetic resonance compatibility in accordance with:
    - ASTM F2052-21, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, and
    - ASTM F2213-17, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.*

- All devices combined, for biocompatibility in accordance with:
    - ISO 10993-1:2018, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,*
    - ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process,*
    - ISO 18562-2:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter,*
    - ISO 18562-3:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds,* and
    - ISO 18562-4:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate.*
- All devices combined, for human factors in accordance with:
    - FDA's guidance, *Applying Human Factors and Usability Engineering to Medical Devices (2016)*
    - FDA's guidance, *Content of Human Factors Information in Medical Device Marketing Submissions (2022)*
    - IEC 62366-1, *Edition* 1.1 2020-06 *Consolidated Version, Medical devices - Part 1: Application of usability engineering to medical device*
- The packaging of all devices, for ability to withstand expected shipping conditions, in accordance with *ISTA 3A:2008, Packaged-products for parcel delivery system shipment 70 kg (150 lb) or less.*

- All devices, at the end of their shelf life, for continued compliance with performance requirements.

Conclusion

The results of these tests support the conclusion that The BAG manual resuscitator and accessories perform acceptably and do not raise any different questions regarding safety or effectiveness compared to the predicate devices, thus supporting a determination of substantial equivalence.