December 7, 2018

Flexicare Medical Limited
% Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K181583
Trade/Device Name: Flexicare Single Use Resuscitator Bags
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual emergency ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: November 20, 2018
Received: November 21, 2018

Dear Dave Yungvirt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181583

Device Name
Flexicare Single Use Resuscitator Bags

Indications for Use *(Describe)*

Flexicare's Adult Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of adult patients with a body weight of more than 66lbs (30kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.

Flexicare's Pediatric Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of infants and children with a body weight of 22lbs to 66lbs (10-30kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.

Flexicare's Infant Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of neonates and infants with a body weight of up to 22lbs (10kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital 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 K181583

510(k) Sponsor, Contact Person and Date Summary Prepared:

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Summary prepared on: November 14th, 2018

Device Name:

Trade Name: Flexicare Single Use Resuscitator Bags

Common/Usual Name: Resuscitator Bag

Classification Name: Ventilator, Emergency, Manual (Resuscitator): 21 CFR 868.5915

Product Codes: BTM (Manual emergency ventilator)

Legally Marketed Equivalent Device:

Flexicare's Adult Single Use Resuscitator Bag is substantially equivalent to Ambu's SPUR II Adult Single Patient Use Resuscitator cleared under K042682.

Flexicare's Pediatric Single Use Resuscitator Bag is substantially equivalent to Ambu's SPUR II Pediatric Single Patient Use Resuscitator cleared under K042843.

Flexicare's Infant Single Use Resuscitator Bag is substantially equivalent to Ambu's SPUR II Infant Single Patient Use Resuscitator cleared under K042843.

Device Description:

Flexicare's Single Use Resuscitator Bags are Single Use devices For manual ventilation of a patient by trained operators in emergency/critical situations where short term ventilation is demanded by the patient's medical condition (e.g. inadequate or no breathing). Manual squeezing of the resuscitator bag forces air or air /O_2 mixture into the patient's lungs via a face mask or pre-positioned airway tube with a 15mm male connection. A reservoir bag is present at the distal end of the device which fills with supplementary O_2 (if using). This can be squeezed into the resuscitator for administration if required.

Flexicare's Single Use Resuscitator Bags feature a one-way duck bill valve at the patient end to deliver fresh gas to the patient whilst preventing ingress of exhaled air and potential re-breathing. A one-way valve is also present at the distal end of the device, ensuring that upon

Flexicare's Single Use Resuscitator Bags feature a one-way duck bill valve at the patient end to deliver fresh gas to the patient whilst preventing ingress of exhaled air and potential re-breathing. A one-way valve is also present at the distal end of the device, ensuring that upon squeezing the Resuscitator bag air only travels toward the patient, and upon release of a squeezed bag fresh ambient air with/without supplementary O_2 is drawn in.
Flexicare's Single Use Resuscitator Bags incorporate a pressure relief valve. This valve limits the pressure within the resuscitator and patient lungs to 60cmH_2O (Adult) or 40cmH_2O (Adult, Pediatric, Infant). One variant of Flexicare's Adult Single Use Resuscitator Bags does not feature a pressure relief valve.

Flexicare's Single Use Resuscitator Bags are comprised of disposable components including a compression bag, valves, tubing and connectors. The Single Use Resuscitator Bags are intended for Adult, Pediatric and Infant patients, are supplied non sterile and are for use by CPR-trained personnel only within a hospital and/ pre-hospital environments.

Intended Use:

Flexicare's Adult Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of adult patients with a body weight of more than 66lbs (30kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.

Flexicare's Pediatric Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of infants and children with a body weight of 22lbs to 66lbs (10-30kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.

Flexicare's Infant Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of neonates and infants with a body weight of up to 22lbs (10kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.

Substantial Equivalence:

Flexicare's Single Use Resuscitator Bags have the same intended use as the predicate devices.
Flexicare's Single Use Resuscitator Bags and the predicate devices are Single Use non-reusable devices. Supplied in Adult, Pediatric and Infant sizes.

Flexicare's Single Use Resuscitator Bags, along with their marketed predicate devices belong to FDA code BTM, and are classified as lifesaving or sustaining devices.

Patient Contact – Skin Contact & Externally Communicating – Limited duration <24hrs (less than 1hr actual use).

Neither Flexicare's Single Use Resuscitator Bags nor the predicate devices by Ambu require software to operate/function.

Both manufacturers' devices are able to be used with industry standard devices such as monitoring lines, face masks, ET tubes and catheter mounts.
Both Flexicare's Single Use Resuscitator Bags and the predicate devices by Ambu are designed for the same intended use in the same intended conditions.
Both manufacturers' devices consist of components made from injection molded, injection blow molded & extruded polymers.
During comparison testing it was determined that there were no invasive components in either of the manufacturer's devices.

The compression bag of Flexicare's devices is a soft TPE, whilst the compression bag of Ambu's devices is noted as SEBS. However, SEBS is a Thermoplastic Elastomer (TPE) and no substantial differences between bag performance were noted during performance testing.
O_2 delivering tubing of both the Flexicare and predicate devices is manufactured from PVC.
Both manufacturers' device's feature a main compression bag along with a supplementary oxygen reservoir bag. Both manufacturers' device's also feature a Medication port and luer lock CO_2 monitoring port at the patient end.
All conical connectors and luer lock connectors on both Flexicare and Predicate devices are compliant with ISO 5356-1:2004 and BS EN 1707:1997 respectively.

The compression bag of Flexicare's Single Use Resuscitator Bags is blue, with remaining components being blue or colorless/transparent. All caps and valves are blue in color. The compression bag of Ambu's Resuscitator bags is colorless/translucent, whilst remaining components such as connectors, valves and caps are either clear/transparent, red or white.

Any differences in color between the Flexicare devices and the predicate devices is by manufacturer's aesthetics choice/ branding, and is not related to sizing, intended use, gender of patient or performance of device.

Both manufacturer's devices are supplied with oxygen tubing, a face mask and an O_2 reservoir bag.

Both Flexicare's Single Use Resuscitator Bags and the predicate devices' O_2 tubes terminate with a connector for securing to an oxygen source.

Both Flexicare's Single Use Resuscitator Bags and the predicate devices by Ambu have gripping/ securing aids, texture and branding molded into the compression bag.

Both Flexicare's Single Use Resuscitator Bags and the predicate devices by Ambu have hand straps to provide additional grip security to the user whilst in operation. The Ambu Devices have a hand strap molded as part of the compression bag, whilst the Flexicare devices feature a removable hand strap that can be adjusted to suit user.

Both devices feature a medication port at their patient end connector sealed by a soft polymer cap, through which drugs can be introduced using a needle and syringe if required. Both devices have been tested with Epinephrine, Lidocaine and Atropine.

Substantial equivalence comparison table – Adult Resuscitator Bags

Flexicare's Adult Single Use Resuscitator Bag is substantially equivalent to SPUR II Adult Single Patient Use Resuscitator manufactured by Ambu (510(k) K042682).

The Table below shows the similarities and differences between the Flexicare's Adult Single Use Resuscitator Bags and the Adult predicate device manufactured by Ambu.

Characteristic compared	**Flexicare's Adult Single Use Resuscitator Bag**	**Ambu SPUR II Adult Single Patient Use Resuscitator**
510K	K: Unknown	K:042682
Intended use	Flexicare's Adult Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of adult patients with a body weight of more than 66lbs (30kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.	The Ambu SPUR II Adult Single Patient Use Resuscitator is intended for pulmonary resuscitation and emergency respiratory support of adult patients with a body weight more than 66lbs (30kg). Source: K042682 SE letter from FDA
Target population	Adult >30kg	Adult >30kg
Patient connection	Face Mask, ET tube	Face Mask, ET tube
Indications for use	Instruction leaflet	Instruction leaflet
Environment used	Hospital, Pre-hospital	Hospital, Pre-hospital
Product labelling	Single Use Resuscitator Bag	Single Patient Use Resuscitator
Volume (ml)	1490ml	1475ml
O_2 Tube Dimensions	OD: 5.0mm ID: 3.9mm LENGTH: 3.0M	OD: 5.0mm ID: 3.9mm LENGTH: 2.0M
Component materials	Compression bag – TPE Connectors - ABS Valves – Silicone O_2 Tubing - PVC Reservoir bag - PVC Face mask - PVC Valve spring – Stainless Steel	Compression bag – SEBS (TPE) Connectors - ABS Valves – Silicone O_2 Tubing - PVC Reservoir bag - PVC Face mask - PVC Valve spring – Stainless Steel
Maximum pressure relief (cmH_2O)	Available in: 60cmH2O 40cmH2O Plain (no pressure relief valve)	Available in: Plain (no pressure relief valve)
Available ports at patient end	• Medication port– Standard luer slip • Manometer • CO_2 monitoring – Standard luer lock	• Mediport (Medication port) – Standard luer slip • Manometer • CO_2 monitoring – Standard luer lock
Option for PEEP	Yes – 30mm Male (ISO)	Yes – 30mm Male (ISO)

valve attachment		
Critical dimensions (mm)	Compression bag length: 180mm Compression bag diameter: 127mm Device assembly length: 640.3mm	Compression bag length: 190mm Compression bag diameter: 118mm Device assembly length: 530mm
Inspiratory Resistance (cmH_2O)	1.5cmH_2O @ 50L/min	2.6 cmH_2O @ 50L/min
Expiratory Resistance (cmH_2O)	1.7cmH_2O @ 50L/min	3.0cmH2O @ 50L/min
Force to compress bag	11.3N	13N
Deadspace (ml)	4.27ml	5.08ml
Stroke Volume - One Hand (ml)	700ml	640ml
Stroke Volume - Two Hands (ml)	850ml	890ml
Supplied Mask size	Adult – size 5	"Medium"
Compatibility with the environment and other devices.	Compatible with ISO 5356-1:2004 and BS EN 1707:1997 compliant connectors	Compatible with ISO 5356-1:2004 and BS EN 1707:1997 compliant connectors
Energy used and or delivered	No energy is delivered to patient. Ambient air or ambient air with supplemental O_2 is supplied to the patient by manually compressing the device.	No energy is delivered to patient. Ambient air or ambient air with supplemental O_2 is supplied to the patient by manually compressing the device.
Sterility	Non-Sterile	Non-Sterile
Standards Met	BS EN ISO 10651-4:2009 ISO 10993 ISO 5356-1:2004 BS EN 13544-2:2002+A1:2009 BS ISO 18562-2 2017	BS EN ISO 10651-4:2002 ASTM F 920-93
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Non-clinical Test Results	Verification tests were performed to establish the safety and efficacy of Flexicare's Adult Single Use Resuscitator Bag. These Non-clinical tests included Visual inspection/comparison, Dimensional inspection, Internal Volume, Valve function, Drop testing, immersion in water, oxygen concentration, expiratory resistance, inspiratory resistance, valve malfunction, tidal volume calculation, O_2 tube tensile testing, O_2 tube resistance to flow, O_2 tube resistance to kinking, conical connector compliance, Biocompatibility testing and Particulate emission testing. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
Conclusion	Flexicare's Adult Single Use Resuscitator Bag is considered to be substantially equivalent to the Ambu SPUR II Adult Single Patient Use Resuscitator. The comparison of features, performance, materials and intended use demonstrate that Flexicare's Adult Single Use Resuscitator Bag is as safe and effective as the predicate device for its intended purpose.	

Substantial equivalence comparison table – Pediatric Resuscitator Bags

Flexicare's Pediatric Single Use Resuscitator Bag is substantially equivalent to SPUR II Pediatric Single Patient Use Resuscitator manufactured by Ambu (510(k) K042843).

The Table below shows the similarities and differences between the Flexicare's Pediatric Single Use Resuscitator Bags and the Pediatric predicate device manufactured by Ambu.

Characteristic compared	**Flexicare's Pediatric Single Use Resuscitator Bag**	**Ambu SPUR II Pediatric Single Patient Use Resuscitator**
510K	K: Unknown	K:042843
Intended use	Flexicare's Pediatric Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of infants and children with a body weight of 22lbs to 66lbs (10-30kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.	The Ambu SPUR II Pediatric Single Patient Use Resuscitator is intended for pulmonary resuscitation and emergency respiratory support of infants and children with a body weight up to 66lbs (30kg), approx. 9 years of age. Source: K042843 SE letter from FDA
Target population	Pediatric 10-30kg	Pediatric <30kg
Patient connection	Face Mask, ET tube	Face Mask, ET tube
Indications for use	Instruction leaflet	Instruction leaflet
Environment used	Hospital, Pre-hospital	Hospital, Pre-hospital
Product labelling	Single Use Resuscitator Bag	Single Patient Use Resuscitator
Volume (ml)	635ml	635ml
O_2 Tube Dimensions	OD: 5.0mm ID: 3.9mm LENGTH: 3.0M	OD: 5.0mm ID: 3.9mm LENGTH: 2.0M
Component materials	Compression bag – TPE Connectors - ABS Valves – Silicone O_2 Tubing - PVC Reservoir bag - PVC Face mask - PVC Valve spring – Stainless Steel	Compression bag – SEBS (TPE) Connectors - ABS Valves – Silicone O_2 Tubing - PVC Reservoir bag - PVC Face mask - PVC Valve spring – Stainless Steel
Maximum pressure relief (cmH_2O)	40cmH2O	40cmH2O
Available ports at patient end	• Medication port– Standard luer slip • Manometer • CO_2 monitoring – Standard luer lock	• Mediport (Medication port) – Standard luer slip • Manometer • CO_2 monitoring – Standard luer lock
Option for PEEP valve	Yes – 30mm Male (ISO)	Yes – 30mm Male (ISO)

attachment		
Critical dimensions (mm)	Compression bag length: 130mm Compression bag diameter: 101mm Device assembly length: 590.3mm	Compression bag length: 130mm Compression bag diameter: 90mm Device assembly length: 439mm
Inspiratory Resistance (cmH_2O)	1.5 cmH_2O @ 50L/min	2.2 cmH_2O @ 50L/min
Expiratory Resistance (cmH_2O)	1.7cmH_2O @ 50L/min	3.0cmH2O @ 50L/min
Force to compress bag	10N	12N
Deadspace (ml)	5.01ml	5.64ml
Stroke Volume - One Hand (ml)	450ml	390ml
Stroke Volume - Two Hands (ml)	N/A	N/A
Supplied Mask size	Pediatric – size 2	"Toddler"
Compatibility with the environment and other devices.	Compatible with ISO 5356-1:2004 and BS EN 1707:1997 compliant connectors	Compatible with ISO 5356-1:2004 and BS EN 1707:1997 compliant connectors
Energy used and or delivered	No energy is delivered to patient. Ambient air or ambient air with supplemental O_2 is supplied to the patient by manually compressing the device.	No energy is delivered to patient. Ambient air or ambient air with supplemental O_2 is supplied to the patient by manually compressing the device.
Sterility	Non-Sterile	Non-Sterile
Standards Met	BS EN ISO 10651-4:2009 ISO 10993 ISO 5356-1:2004 BS EN 13544-2:2002+A1:2009 BS ISO 18562-2 2017	BS EN ISO 10651-4:2002 ASTM F 920-93
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Non-clinical Test Results	Verification tests were performed to establish the safety and efficacy of Flexicare's Adult Single Use Resuscitator Bag. These Non-clinical tests included Visual inspection/comparison, Dimensional inspection, Internal Volume, Valve function, Drop testing, immersion in water, oxygen concentration, expiratory resistance, inspiratory resistance, valve malfunction, tidal volume calculation, O_2 tube tensile testing, O_2 tube resistance to flow, O_2 tube resistance to kinking, conical connector compliance, Biocompatibility testing and Particulate emission testing. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
Conclusion	Flexicare's Pediatric Single Use Resuscitator Bag is considered to be substantially equivalent to the Ambu SPUR II Pediatric Single Patient Use Resuscitator. The comparison of features, performance, materials and intended use demonstrate that Flexicare's Pediatric Single Use Resuscitator Bag is as safe and effective as the predicate device for its intended purpose.	

Substantial equivalence comparison table – Infant Resuscitator Bags

Flexicare's Infant Single Use Resuscitator Bag is substantially equivalent to SPUR II Infant Single Patient Use Resuscitator manufactured by Ambu (510(k) K042843).

The Table below shows the similarities and differences between the Flexicare's Infant Single Use Resuscitator Bags and the Infant predicate device manufactured by Ambu.

Characteristic compared	**Flexicare's Infant Single Use Resuscitator Bag**	**Ambu SPUR II Infant Single Patient Use Resuscitator**
510K	K: Unknown	K:042843
Intended use	Flexicare's Infant Single Use Resuscitator Bag is intended for manual pulmonary resuscitation and emergency respiratory support of neonates and infants with a body weight of up to 22lbs (10kg). For use with ambient air and supplemental oxygen if required. For use by CPR-trained personnel only within hospital and/ pre-hospital environments.	The Ambu SPUR II Infant Single Patient Use Resuscitator is intended for pulmonary resuscitation and emergency respiratory support of neonates and infants with a body weight up to 22lbs (10kg) Source: K042843 SE letter from FDA
Target population	Infant <10kg	Infant <10kg
Patient connection	Face Mask, ET tube	Face Mask, ET tube
Indications for use	Instruction leaflet	Instruction leaflet
Environment used	Hospital, Pre-hospital	Hospital, Pre-hospital
Product labelling	Single Use Resuscitator Bag	Single Patient Use Resuscitator
Volume (ml)	370ml	220ml
O_2 Tube Dimensions	OD: 5.0mm ID: 3.9mm LENGTH: 3.0M	OD: 5.0mm ID: 3.9mm LENGTH: 2.0M
Component materials	Compression bag – TPE Connectors - ABS Valves – Silicone O_2 Tubing - PVC Reservoir bag - PVC Face mask - PVC Valve spring – Stainless Steel	Compression bag – SEBS (TPE) Connectors - ABS Valves – Silicone O_2 Tubing - PVC Reservoir bag - PVC Face mask - PVC Valve spring – Stainless Steel
Maximum pressure relief (cmH_2O)	40cmH2O	40cmH2O
Available ports at patient end	• Medication port– Standard luer slip • Manometer • CO_2 monitoring – Standard luer lock	• Mediport (Medication port) – Standard luer slip • Manometer • CO_2 monitoring – Standard luer lock
Option for PEEP valve	Yes – 30mm Male (ISO)	Yes – 30mm Male (ISO)

attachment		
Critical dimensions (mm)	Compression bag length: 100mm Compression bag diameter: 87.7mm Device assembly length: 444.3mm	Compression bag length: 75mm Compression bag diameter: 67mm Device assembly length: 417mm
Inspiratory Resistance (cmH_2O)	0.4 cmH_2O @ 5L/min	0.5 cmH_2O @ 5L/min
Expiratory Resistance (cmH_2O)	0.9cmH_2O @ 5L/min	1.6cmH2O @ 5L/min
Force to compress bag	10N	12N
Deadspace (ml)	4.46ml	5.64ml
Stroke Volume - One Hand (ml)	170ml	110ml
Stroke Volume - Two Hands (ml)	N/A	N/A
Supplied Mask size	Infant – size 0	"Neonate"
Compatibility with the environment and other devices.	Compatible with ISO 5356-1:2004 and BS EN 1707:1997 compliant connectors	Compatible with ISO 5356-1:2004 and BS EN 1707:1997 compliant connectors
Energy used and or delivered	No energy is delivered to patient. Ambient air or ambient air with supplemental O_2 is supplied to the patient by manually compressing the device.	No energy is delivered to patient. Ambient air or ambient air with supplemental O_2 is supplied to the patient by manually compressing the device.
Sterility	Non-Sterile	Non-Sterile
Standards Met	BS EN ISO 10651-4:2009 ISO 10993 ISO 5356-1:2004 BS EN 13544-2:2002+A1:2009 BS ISO 18562-2 2017	BS EN ISO 10651-4:2002 ASTM F 920-93
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Non-clinical Test Results	Verification tests were performed to establish the safety and efficacy of Flexicare's Adult Single Use Resuscitator Bag. These Non-clinical tests included Visual inspection/comparison, Dimensional inspection, Internal Volume, Valve function, Drop testing, immersion in water, oxygen concentration, expiratory resistance, inspiratory resistance, valve malfunction, tidal volume calculation, O_2 tube tensile testing, O_2 tube resistance to flow, O_2 tube resistance to kinking, conical connector compliance, Biocompatibility testing and Particulate emission testing. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
	Flexicare's Infant Single Use Resuscitator Bag is considered to be substantially equivalent to the Ambu SPUR II infant Single Patient Use Resuscitator. The comparison of features, performance, materials and intended use demonstrate that Flexicare's Infant Single Use Resuscitator Bag is as safe and effective as the predicate device for its intended purpose.	

Summary of performance Testing: Flexicare's Single Use Resuscitator Bags have been evaluated in accordance with standards listed in table:

Test	Standard / Pre-Determined Acceptance Criteria	Outcome
Visual inspection	Comparison test	Substantially equivalent
Valve Function after contamination with vomitus	BS EN ISO 10651-4:2009	Pass
Mechanical shock - Drop testing		
Immersion in Water		
Supplementary Oxygen & Delivered Oxygen Concentration		
Expiratory Resistance		
Inspiratory Resistance		
Patient Valve Malfunction		
Tidal Volume - Minimum Delivered Volume		
Pressure Limitation - Pressure Relief Blow off		
Conical Connector compliance	ISO 5356-1:2004	Pass
Leak testing		
Drop testing		
Cytotoxicity, Irritation, Sensitization, Systemic Toxicity, Extractables & Leachables.	ISO 10993-10:2010 ISO 10993-5:2009 ISO 10993-11:2009 ISO 10993-17:2009	Pass
Tubing resistance to gas flow	BS EN 13544-2:2002+A1:2009	Pass
Tensile strength – connector to tubing		
Tensile strength – connector to O_2 spout		
Resistance to kinking		
Accelerated Ageing	ASTM F1980	Pass
Particulate Emissions	BS ISO 18562-2 2017	Pass

Flexicare's Single Use Resuscitator Bags passed the performance testing when tested against methods and criteria from both pre-determined acceptance criteria methods and relevant FDA Recognized standards. The results of this testing show that Flexicare's Single Use Resuscitator Bags pass all performance tests and perform substantially equivalent to the marketed predicate devices.

Consensus Standards

ISO 10651-4 and ISO 5356-1 are recognized consensus standards for devices classified through FDA product code BTM.

The Flexicare Single Use Resuscitator Bags passed the performance testing when tested against methods and criteria from relevant FDA Recognized standards. The results of this testing show that The Flexicare Single Use Resuscitator Bags passes all performance & safety tests and perform substantially equivalent to the marketed predicate devices.

Although very similar in design and function there are some differences, as described below, between the Flexicare's Single Use Resuscitator Bags and the predicate devices from Ambu.

Differences:

- The Flexicare Single Use Resuscitator Bags feature an adjustable hand strap to aid in securing the device to user's hands of varying sizes. The Ambu Single Use Resuscitators feature a 1-piece molded strap that is integral to the compression bag.

- The Flexicare Single Use Resuscitator Bags consist of clear/colorless and blue components whereas the Ambu devices consist of clear/colorless, white and red components. However, this difference in color is due to manufacturer branding and in no way reflects sizing, intended use, gender of patient or performance of device.

- Both manufacturer's offer devices with lockable pressure relief valves. However, The Flexicare Single Use Resuscitator Bags feature a compress & twist action to lock the valve whereas the Ambu devices use a pivoted lever to lock the valve in closed position.

- Both manufacturer's devices feature inlet connectors for supplementary oxygen. However, the Ambu devices feature their oxygen inlet connectors at a 90° angle to the horizontal plane of the device. Flexicare's Single Use Resuscitator Bags oxygen inlet connectors are in line with the horizontal plane of the device.

- The Flexicare Single Use Resuscitator Bags feature a 3M O_2 line whilst the Ambu Single Use Resuscitators feature a 2M O_2 line. This difference does not contribute towards device performance. However, the extra 1M length could be seen as a usability advantage to Flexicare's devices.

Conclusion: The overall conclusion from the comparison testing is that Flexicare Single Use Resuscitator Bags are considered to be substantially equivalent to those of the predicate devices manufactured by Ambu, and that Flexicare's Single Use Resuscitator Bags perform substantially equivalent to the marketed predicate devices.