Flexicare Medical Limited
Joel Biddle
Regulatory Manager
Cynon Valley Business Park
Mountain Ash, cf45 4er
United Kingdom

Re: K201666
Trade/Device Name: Single Use Manometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: Class II
Product Code: CAP
Dated: October 12, 2020
Received: October 15, 2020

Dear Joel Biddle:

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 post marketing 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, PhD
Assistant Director (Acting)
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201666

Device Name
Single Use Manometer

Indications for Use *(Describe)*
Flexicare Single Use Manometer is attached to the manometer port on Flexicare resuscitation bags to provide visual indication of the patient's airway pressure during ventilation. The device is intended to be used by trained personnel only within a hospital and/or pre-hospital environment.

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

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

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Summary prepared on: November 13th, 2020

Device Name:

Trade Name: Single Use Manometer

Common/Usual Name: Airway Pressure Monitor

Classification Name: Airway Pressure Monitor: 21 CFR. 868.2600

Product Codes: CAP (Airway Pressure Monitor)

Legally Marketed Equivalent Device:

Flexicare's Single Use Manometer is substantially equivalent to Ambu Disposable Pressure Manometer, cleared under K040991.

Device Description:

Flexicare's Single Use Manometer is a single use device that can be attached to the manometer port on resuscitation bags to provide visual indication of the patient's airway pressure during manual ventilation.

Flexicare's Single Use Manometer consists of end cap, clear housing with printed pressure scale, concertina seal, slider and stainless steel spring. When pressure rises, the spring is compressed raising the blue concertina seal and showing the pressure via markings on the manometer housing has calibrated marking at 20 cmH2O intervals between 0 through 60 cmH2O. The measured pressures are accurate to ± 1cmH2O.

Flexicare's Single Use Manometer is supplied non-sterile and are for use by CPR-trained personnel only within a hospital and/or pre-hospital environments.

Indications For Use:

Flexicare Single Use Manometer is attached to the manometer port on Flexicare resuscitation bags to provide visual indication of the patient's airway pressure during ventilation. The device is intended to be used by trained personnel only within a hospital and/or pre-hospital environment.

Substantial Equivalence:

Flexicare's Single Use Manometer has the same intended use as the predicate device.

Flexicare's Single Use Manometer and the predicate device are Single Use non-reusable devices.

Flexicare's Single Use Manometer, along with its marketed predicate device belongs to FDA code CAP and are not classified as a lifesaving or sustaining device.

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

Neither Flexicare's Single Use Manometer nor the predicate device by Ambu require software to operate/function.

Neither Flexicare's Single Use Manometer nor the predicate device by Ambu require connection to an electronically powered device.

Both Flexicare's Single Use Manometer and the predicate device by Ambu are available non-sterile (in individually sealed polybags).

Both manufacturers' devices consist of components made from injection molded polymers and the housings of each are made from very similar amorphous polymers, providing a very hard, transparent shell.

During comparison inspections it was determined that there were no invasive components in either of the manufacturer's devices.

Neither manufacturer's devices are in vitro diagnostic devices.

The housing of Flexicare's Single Use Manometer is mostly opaque white, with the pressure markings panel being colorless. The end cap is blue color. The Ambu Disposable Pressure Manometer has white cap and color coded pressure markings (green, yellow and red).

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

Both manufacturer's devices are available non-sterile only.

Substantial equivalence comparison table – Flexicare's Single Use Manometer

Flexicare's Single Use Manometer is substantially equivalent to the Ambu Disposable Pressure Manometer, manufactured by Ambu cleared under (510(k) K040991).

The table below shows the similarities and differences between the Flexicare's Single Use Manometer and the predicate device manufactured by Ambu.

	Flexicare's Single Use Manometer	**Ambu Disposable Pressure Manometer**
510(k)	K201666	K040991
Intended Use	Flexicare Single Use Manometer is attached to the manometer port on Flexicare resuscitation bags to provide visual indication of the patient's airway pressure during ventilation. The device is intended to be used by trained personnel only within a hospital and/or pre-hospital environment.	Ambu Disposable Pressure Manometer will be used to provide visual indication of the patient's airway pressure during ventilation. It may be attached to the manometer port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask or CPAP circuits. Source: K040991 510(k) summary
Target population	Patient that the clinician desires to monitor or measure pressure - Adult, Pediatric, Infant	Unspecified
Product Labelling	Single Use Manometer for use with Manual Resuscitator	Ambu ® Disposable Pressure Manometer
Patient Contact	External Communicating	External Communicating
Patient use/Duration of use	Single use, disposable, <24hrs	Single use, disposable, <24hrs
Connects to a sampling port of any device	It may be attached to the manometer port on Flexicare resuscitation bags.	It may be attached to the manometer port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask or CPAP circuits.
Supplied sterile	Non-sterile	Non-sterile
Component materials	End Cap - PVC Concertina Seal - Silicone Slider - ABS Spring - Stainless Steel Housing – ABS Outer Shrink Sleeve - PVC	Connector – SEBS Spring - CuSn Housing - SB Piston - PP Membrane – Silicone (Source: Ambu Datasheet)
Connector size	ID 5.3mm	ID 3.7mm
Color coded	Not color coded	Color coded: • Green: 0 - 20 cmH_2O • Yellow: 20 - 40 cmH_2O • Red: 40 - 60 cmH_2O
Pressure range	0 - 60 cmH_2O	0 - 60 cmH_2O
Display increment	20, 40, 60 cmH_2O	5, 10, 15, 20, 30, 40, 60 cmH_2O

Method of translating in-line pressure	Displacement of concertina seal against spring (counter force)	Displacement of diaphragm against spring (counter force)
Indicator movement	Linear, force pushes the center of concertina seal and extends upward until lines up with pressure indicator label	Linear, force pushes the center of diaphragm, which extends upward until lines up with pressure indicator label
Pressure marking	Printed on outer shrink sleeve and wrap around housing	Pressure increment – tampo printed Color coding - sticker
Performance testing	Accuracy • ± 1 cm H_2O at 20, 40, 60cm H_2O	Accuracy (source: Ambu IFU) • ± 2 cm H_2O at 5, 10, 15, 20, 30 cm H_2O • ± 3 cm H_2O at 40 cm H_2O • ± 5 cm H_2O at 60 cm H_2O
Leak testing	<1 ml/min	<2 ml/min
Repeatability	Passed – within accuracy tolerance	Passed – within accuracy tolerance
Environmental testing	Passed environmental testing at -40°C and +60°C according to ISO 10651-4:2009	Tested at -40°C and +60°C according to EN ISO 10651-4 (source: Ambu IFU)
Drop test	Passed – within accuracy tolerance Mechanical integrity - passed	Passed – within accuracy tolerance Mechanical integrity – one damaged
Shelf Life	5 years	5 years
Packaging	Polybag	Polybag
Standards met	ISO 10993-1 ISO 18562-2 ISO 10651-4	510(K) Summary does not specify
Biocompatibility	ISO 10993 compliant EN ISO 18562 compliant	Not stated
Non-clinical Test Results	Verification tests were performed on Flexicare's Single Use Manometer. These Non-clinical tests included Visual Inspection/Comparison, Degree of Accuracy, Repeatability, Drop Testing, Leak Testing, Shelf Life Verification, Biocompatibility and Particulate Emission. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
Conclusion	Flexicare's Single Use Manometer is considered to be substantially equivalent to the Ambu Disposable Pressure Manometer. The comparison of each device's features, performance, materials, intended use and intended purpose demonstrate this.	

Summary of Performance Testing: Flexicare's Single Use Manometer has been evaluated in accordance with standards listed in table:

Test	Standard / Pre-Determined Acceptance Criteria	Outcome
Visual Inspection	Pre-determined Acceptance Criteria*	Pass
Degree of Accuracy	Pre-determined Acceptance Criteria*	Pass
Repeatability	Pre-determined Acceptance Criteria*	Pass
Leak testing	Pre-determined Acceptance Criteria*	No pass criteria – Comparable performance outcome between Flexicare's device and the predicate devices
Drop testing	ISO 10651-4: 2009	Pass
	ISO 10993-10:2010	Pass

Cytotoxicity, Irritation, Sensitization, Systemic toxicity, Extractables & Leachables.	ISO 10993-5:2009	Pass
	ISO 10993-11:2009	Pass
	ISO 10993-17:2009	Pass
Particulate emissions (gas pathway)	EN ISO 18562-2:2017	Pass
Accelerated Ageing	ASTM F1980	Pass

*** Pre-determined Acceptance Criteria - Visual inspection**
Criteria: Samples are free from any damage or defects.

Methodology: Inspect the packaging of each sample for any damage or defects present, including but not limited to punctures or tears, damaged or misprinted markings, contamination or foreign matter in bag material, dirty marks or foreign matter inside the bag and thinning of bag material. Remove the samples from their packaging and inspect for (but not limited to) missing components, cracked components, incorrect or damaged print, incorrectly positioned sleeve, damaged or deformed spring, blockages inside body, excess molding flash or flash on critical surfaces (e.g. inner wall of body, PVC connector), components not fitting together correctly, discoloration or print / components, correct color of parts (Refer to GA assembly drawing), foreign matter and unable to fit securely to a resus bag. Note any issues and record the result.

*** Pre-determined Acceptance Criteria – Degree of Accuracy and Repeatability**
Criteria: Graduation print and manometer slider overlap at each marked pressure graduation.

Methodology: Connect the digital pressure indicator and Syringe via a T-Piece. Set the Digital Pressure meter to mH_2O. Zero the DPI at atmospheric pressure. Connect the test sample to the T-Piece. Increase the pressure by depressing the syringe plunger to the required pressure graduations marked on the manometer body. At each pressure graduation inspect the manometer slider and check it aligns with the pressure graduation on the manometer housing. Release the pressure and check that the piston returns smoothly back to the original start position. Repeat step 1 - 7 a further 4 times at each pressure marking.

*** Pre-determined Acceptance Criteria – Leak Testing**
Criteria: There is no standard criteria available. Test is for comparative use only.

Methodology: Connect the digital pressure indicator and Syringe via a T-Piece. Set the Digital Pressure meter to mH2O. Zero the DPI at atmospheric pressure. Connect the test sample to the T-Piece. Depress the syringe plunger to raise the internal pressure of the filter to 65cmH2O. Note the initial volume of the syringe and begin timing. Maintain the pressure at 65cmH2O for 1 minute, by adding air as necessary with the syringe. After one minute, note the new volume of the syringe. Calculate the leakage rate per minute: Leakage (ml/min) = Initial Volume (ml) – New Volume (ml)

Flexicare's Single Use Manometer 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 Manometer passes all performance tests and perform at least as well as the marketed predicate device.

Consensus Standards

There is no recognized consensus standard for devices classified through FDA product code CAP.

Device differences

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

Differences:

- The housing of Flexicare's Single Use Manometer is mostly opaque white, with the pressure markings panel being colorless. The end cap is blue color. The Ambu Disposable Pressure Manometer has green, yellow and red color coded scale and white cap. However, this difference in color is due to manufacturer branding and in no way reflects standard criteria, sizing, intended use, gender of patient or performance of device. The color coded scale on Ambu Disposable Pressure Manometer is only for visual support. The correct ventilation pressure must be determined by the medical professional.

- Flexicare's Single Use Manometer has calibrated marking at 20 cmH2O intervals, whereas Ambu Disposable Pressure Manometer has calibrated marking at 5, 10, 15, 20, 30, 40, 60 cmH2O.

- Flexicare's Single Use Manometer has pressure marking printed on outer shrink sleeve and wrap around housing whereas the pressure increment on Ambu Disposable Pressure Manometer is tampo printed and the color coding is printed on a sticker.

- The internal diameter of connector in Flexicare's Single Use Manometer is 5.3mm whilst Ambu Disposable Pressure Manometer features a connector with 3.7mm internal diameter. However, there is no standard requirement for the connector dimension of manometer. Flexicare's Single Use Manometer is only designed to be attached to the manometer port on Flexicare resuscitation bags. According to Ambu IFU, Ambu Disposable Pressure Manometer can be attached to the manometer port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask or CPAP circuits.

- The size of Flexicare's Single Use Manometer (length 43.6mm, diameter 21mm) is slightly smaller than Ambu Disposable Pressure Manometer (length 55mm, diameter 22mm). However, there is no standard requirement for the specific length of manometer. This difference in dimension did not impact on devices ability to perform to a comparative level when conducting substantial equivalence testing within CTR-000006 test report.

Conclusion:

The overall conclusion from the comparison testing is that Flexicare's Single Use Manometer is considered to be substantially equivalent to the predicate device manufactured by Ambu, and that Flexicare's Single Use Manometer performs at least as well as the marketed predicate device.