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K094003

5. "510(k) SUMMARY"

SEP 17 2010

"510(k) SUMMARY"

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

- SUBMITTER´S NAME: HERSILL, S.L.
- ADRESS: Puerto de Navacerrada, 3, 28935 Móstoles, Madrid, SPAIN
- TELEPHONE NUMBER: +34 91 616 41 11
- CONTACT PERSON: Miguel Óscar Martínez Jordán
- DATE (mm/dd/yyyy): 12/11/2009

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

- Trade Name: REVIVATOR
- Models:
  - REVIVATOR PLUS (adult, child, enfant)
  - REVIVATOR RES-Q (adult, child)
  - REVIVATOR KITS (PLUS, RES-Q)
- Classification name:
  - Device: Ventilator, emergency, Manual (Resuscitator)
  - Product Code: BTM
  - Regulation Number: 868.5915
  - Regulation description: Manual emergency ventilator

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

Submiter: Ambu, Inc.

- Ambu neonate silicone resuscitator (K993278)

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- Ambu silicone resuscitator adult (K924215)
- Ambu silicone infant/child (K924216)
- Ambu spur II adult single patient resuscitator (K042682)
- Ambu Spur II infant and paediatric single (K042843)

Submitter: Mercury Medical

- Mercury medical disposable CPR bag (K911622)
- Mercury medical reusable CPR bag (K970756)

(4) Device description

Functioning and scientific concepts

A resuscitator is a device using positive pressure to inflate the lungs of an unconscious person who is not breathing, in order to keep him oxygenated and alive. The manual resuscitators basically consist of a mask and a large hand-squeezed plastic bulb using ambient air, or supplemental oxygen.

The air and oxygen flows into the resuscitator bag.(Fig. 1, Fig. 2, Fig. 3). And compressing the bag, the patient is ventilated.

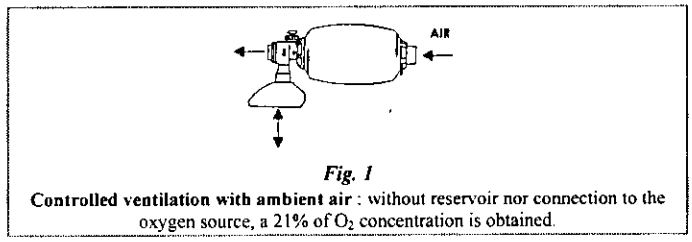

Fig. 1
Controlled ventilation with ambient air : without reservoir nor connection to the oxygen source, a 21% of O_2 concentration is obtained.

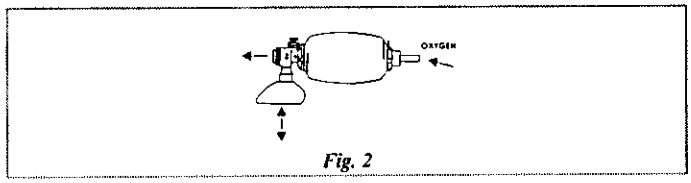

Fig. 2

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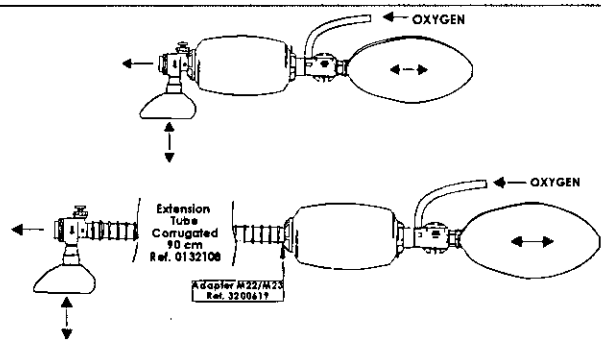

Fig. 3

Controlled ventilation with supplemental oxygen with (Fig. 3) or without (Fig. 2) reservoir: the use of additional O_2 allows to obtain an adjustable concentration from 21 up to 100%, according to the flow of the O_2 source. This is the recommended practise by all the actual resuscitation guidelines. The use of the reservoir allows a saving of O_2 upper than 50%.

In order not to apply a high pressure to the patient's airways, the resuscitators include a pressure-limiting valve.

- Child/infant resuscitators: the pressure-limiting valve is set to open at 45 cm H_2O. If higher pressures are required, press to block (no lock)
- Adult resuscitators: the pressure-limiting valve is set to open at 60 cm H_2O. if higher pressures are required, press and turn to lock

Components (Fig. 8):

- Reservoir bag
- Reservoir valve
- Beg inlet valve
- Resuscitator Bag
- Patient valve
- Pressure-limiting valve

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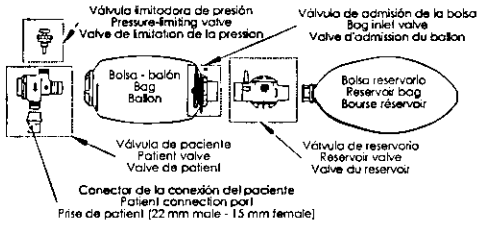

Fig.8

Technical specifications:

(1) Dimensions and weight

Dimensions extended	310L x 130H mm adult 257L x 103H mm child 228L x 80H mm infant
Dimensions folded	125L x 90H mm adult 125L x 85H mm child
Weight	341 g adult 246 g child 233 g infant
Total bag volume	1700 mL adult 750 mL child 300 mL infant
O_2 reservoir volume	2500 mL (adult-child) 500 mL (infant)

Environmental conditions

Storage temperature	-40°C to +70°C -104°F to +158°F
Operating temperature	-20°C to +60°C -68°F to +140°F

Tidal volume

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Maximum tidal volume	1000mL adult 500mL child 200mL infant

Test specifications:

Hand: EN ISO 10651-4
C=0,05L/mbar x 2
R=2mbar/(L/s) x 2

Pressure-limiting system

Safety valve incorporated in all models (it can be locked in the adult model).

Pressure-limiting valve	6 kPa = 60 cm H_2O (Adult) 4,5kPa = 45 cm H_2O (Child-Infant)

Frequency of ventilation

Max. Ventilatory frequency [breaths / min.]	40 (adult) 50 (child) 90 (infant)	Test specs.: C=0,05L/mbar x 2 R=8mbar/(L/s) x 2
Max.ventilation pressure [cmH_2O]	30 (adult) 30 (child) 20 (infant)	Test specs.: C=0,05L/mbar x 2 R=8mbar/(L/s) x 2

Its freedom of rotation of 360° of the mask and the valve of the patient allows to easily ventilate from any position.

Deadspace:

Dead space of patient valve	Lower than 7 mL

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Expiratory and inspiratory resistance

Expiratory resistance	8,8Pa = 0,09cmH_2O at 5L/min. 172Pa=1,76cmH_2O at 50L/min.
Inspiratory resistance	36Pa = 0,37cmH_2O at 5L/min. 341Pa=3,48cmH_2O at 50L/min.

Connectors:

- Patient connector: 22mm male / 15mm female
- Expiratory connector: 30mm male (PEEP/AGSS). The expiratory port is normalized to be able to incorporate PEEP.
- Reservoir valve connector: 32 mm female
- Reservoir bag connector: 25 mm male
- O_2 Connector 5,5–8 mm conical male

Delivered oxygen concentration

	2	3	8	13	15	L/min
Without reservoir	39	39	58	61	88	% O2
With reservoir	98	98	98	100	100	% O2

(7) Accessories:

Ref.	ACCESORIES
0200032	Transport case (434 g, 345 x 145 x 140 mm)
4200601	Adult patient valve
4200602	Child / infant patient valve
3200618	Hand strap
4200605	Reservoir valve
3200505	O_2 reservoir bag 500 mL (230 x 95 mm)

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3200504	O_2 reservoir bag 2500 mL (285 x 135 mm)
3200010	O_2 pipe extension (2 m)
0200045	Silicone mask n° 5
0200044	Silicone mask n° 4
0200043	Silicone mask n° 3
0200042	Silicone mask n° 2
0200041	Silicone mask n° 1
0200040	Silicone mask n° 0
3200501	PEEP valve 2-10 cmH_2O
3200502	PEEP valve 5-20 cmH_2O
0132044	Bacterial/viral filter
0132045	Membranes filter sterile (x 40)
4200606	Air way manometer
0140015	Holder ring for head strap
0131344	Head strap wring
3200619	Adapt.M22 / M23
0132108	Extension tube corrugated (90 cm)
3200621	Adapt. F30-F32 AGSS/reservoir
4200603	Repairing kit
0200049	Cover mask (adult, child)
0200048	Cover mask (infant)

Materials

	Revivator Plus	**Revivator Res-Q**
Transport case	PP (polypropylene)	PP (polypropylene)
Transparent resuscitator parts	PSU (polysulfone)	PC (polycarbonate)
Resuscitator bag	SI (silicone)	SI (silicone)
Valve's membranes	SI (silicone)	SI (silicone)
Relief valve spring	Stainless Steel	Stainless Steel
Relief valve closing	SI (silicone)	SI (silicone)
Mask	SI (silicone)	PVC
o-rings	Viton®	Viton®
Hand strap	Silicone	Silicone
Reservoir bag	PVC	PVC
O2 pipe extension (2 m)	PVC	PVC

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PEEP valve	PSU+SI+S.Steel	PSU+SI+S.Steel
Adapt.M22 / M23	PA-66 (polyamide)	PA-66 (polyamide)
Extension tube corrugated	SI (silicone)	SI (silicone)
Adapt.F30-32 AGSS/reservoir	PA-66 (polyamide)	PA-66 (polyamide)
Bacterial/viral filter	PSU (polysulfone)	PSU (polysulfone)
Holder ring for head strap	Stainless Steel	Stainless Steel
Head strap wring	Isopren (latexfree) Autoclavable 134 °C	Isopren (latexfree) Autoclavable 134 °C
Cover mask	PSU	PSU

(5) Intended use.

The Revivator resuscitator is intended for pulmonary resuscitation.
The adult resuscitator is for people with a body weight of more than 30 kg (66 lbs)
The child resuscitator is for children with a body weight between 7 and 30 kg (15-66 lbs)
The infant resuscitator is for infants with a body weight up to 7 kg (15 lbs)

(6) Technological characteristics comparison

Comparing with the predicate devices, there are no substantial changes or modifications.

Intended use:

Both Revivator resuscitators, Ambu and Mercury Medical resuscitators are intended for pulmonary resuscitator.

Indications for use:

The different models are indicated for different people according to their weight.

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5. "510(k) SUMMARY"

All adult resuscitators are intended for people with a body weight of more than 30 kg (66 lbs).

Revivator and Mercury medical child resuscitators and are for children with a body weight between 7 and 30 kg (15-66 lbs) and infant resuscitators are for people with a body weight up to 7 kg.

However, Ambu child resuscitator are for people with a body weight between 10 and 30 kg and neonate or infant resuscitators are for neonates or infants with a body weight up to 10 kg.

The limit of 7 kg (Revivator resuscitators and Mercury medical resuscitators) or 10 kg (Ambu resuscitators) are not important to classify a resuscitator. Nevertheless, the mass is important for other requirements of ISO 10651-4:2002 (See Pressure limiting valve, maximum tidal volume and dead space comparison)

Standards

Revivator and Ambu resuscitators have been designed and manufactured according to ISO 10651-4:2002 : Lung ventilators . Part 4.: Particular requirements for operator-powered resuscitators.

Moreover, Revivator and Ambu are in conformity with the Medical Devices Directive 93/42/EEC.

Mercury medical resuscitators meet ASTM F 920-93 and ISO 8382 requirements. Nevertheless, ASTM F920-93 has been withdrawn and ISO 8382 was revised by ISO 10651-4:2006.

Main materials and sterilization process:

The materials used for the manufacturing of resuscitators determine the resuscitator shelf life.

In this way, we can compare Revivator Plus and Res-Q with Ambu silicone Plus resuscitators and Mercury Medical reusable resuscitators.

The main material of Revivator resuscitator is silicone (bag and valves).
Depending on the model, the rest of plastic pieces are made of polisulfone (Revivator Plus), or policarbonate (Revivator Res-Q).

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The shelf life and the reuse of resuscitators depends on the plastic material. Polisulfone pieces can be sterilized at 135 °C and polycarbonate pieces at 121°C.

The design of Revivator Plus and Revivator Res-Q is the same, but the plastic pieces of Revivator Res-Q are made of polycarbonate (PC) instead of polysulfone (PSU). Polycarbonate pieces are completely safe. The difference is the material resistance to heat. So, PC pieces cannot be sterilized at temperatures higher than 121°C.

Ambu silicone resuscitators and Mercury Medical resuscitators are also made of silicone (bag and valves) and polisulfone (the rest of plastic pieces). So they can be also sterilized at 134°C.

Both Ambu silicone resuscitator and Revivator Plus has reservoir bags made of PVC and silicone oxygen masks. Moreover, the PVC bag and the silicone masks included in Revivator resuscitators have been also biocompatibility tested.

Regarding Mercury Medical disposable resuscitators, the materials are unknown, since they are not included in their labeling.

Revivator Res-Q includes single use oxygen mask (PVC masks). Ambu Spur II also offers disposable oxygen masks. PVC masks included in Revivator Res-Q has been also biocompatibility tested.

Dimensions and weight

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All resuscitators have similar dimensions and weights. The lower dimensions and weight of neonate/infant Ambu resuscitators (see table) is due to that they do not include the weight of the mask and the dimension of the reservoir bag.

Storage and operating temperatures

Storage and operating temperatures are similar for all resuscitators but, the operating temperature for Ambu Spur II is up to 60ºC instead of 70ºC. This is due to Ambu Spur II use some materials such us SEBS and polyethylene that have lower resistance to temperatures.

Maximum tidal volume and total bag volume

The total bag volume is in relation with the maximum tidal volume. So the maximum tidal volume is the parameter to compare.

According to ISO the maximum tidal volume shall be at least:

- 150 mL for resuscitators for people with a body weight lower than 10 kg
- 450 mL for resuscitators for people with a body weight between 10 and 40 kg
- 600 mL for resuscitators for people with a body weigh higher than 40 kg

Therefore, all resuscitators are according to this standard.

O2 reservoir volume

The reservoir volume is in relation with the delivery oxygen concentration when using supplemental oxygen. ISO 10651-4:2002 requires that resuscitators supplied an oxygen concentration at least 85%. (V/V)
As Revivator and Ambu resuscitators are in conformity with this standard, the reservoir volumes (2500-2600 mL or 300-500 mL) are appropriate to meet this requirement.
Mercury Medical resuscitators have also similar O2 reservoir volumes

Moreover, 2500 mL or 2600 mL are common values for adult reservoir bags and 600, 500 and 300 mL are commonly used for infant resuscitators.

Pressure-limiting valve

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5. "510(k) SUMMARY"

The ISO 10651-4:2002 says that all resuscitators intended for use with people with a body weight lower than 10 kg shall have a pressure limitation system.
The pressure shall not be higher than 4.5 kPa.

Revivator resuscitators for child and infants has a pressure limiting valve at 4.5 kPa
Ambu silicone resuscitators and Ambu Spur II for child and infant has also a pressure limiting valve at 4.0 kPa.
Mercury medical resuscitators (child and infant models) have also a pressure-limiting valve at 4.0 ± 0.5 kPa
Both 4.5 kPa and 4.0 kPa are admissible according to the standard. So they can be considered safe and equivalent.

Revivator resuscitaros for adults also include a pressure limiting valve at 6 kPa and Ambu Spur II has also available a pressure limiting valve at 4,0 kPa. Mercury medical resuscitators have also an optional pressure limiting valve for small adults
ISO 10651-4:2002 considers this option for resuscitators for people with a body weight higher than 10 kg. The pressure shall be lower than 6 kPa. Therefore both resuscitators meet ISO 10651-4:2002 and they can be considered as safe devices.

Dead space of patient valve

The dead space for Revivator is lower than 7 mL. The predicate devices has a dead space lower between 5 and 7 mL.
The differences of the dead space between Revivator, Ambu and Mercury Medical do not raise safety concerns, since according to the ISO 10651-4:2002 the apparatus dead space shall not exceed 5 mL +10 % of the minimum delivered volume.

According to Table 1, ISO 10651-4:2002	Deadspace
B <5 , Vdel=20 mL	<7 mL
5<B<10, Vdel= 150 mL	20 mL
10<B<40, Vdel=15xB mL	
B>40, Vdel=600mL	65 mL

Therefore, values lower than 7 ml of dead space for Revivator resuscitators are completely admissible and it does not affect the safety and effectiveness of the resuscitators.

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Expiratory resistance

According to ISO 10651-4:2002, the expiratory resistance shall not exceed 5 cm H_2O

Revivator, Ambu and Mercury Medical resuscitators have values much lower than the admissible value.

Moreover, to facilitate exhalation, expiratory resistance should be minimized. Since Revivator resuscitators have lower expiratory resistance than predicate devices, Revivator resuscitators facilitate a better exhalation comparing with the predicate devices

Inspiratory resistance

According to ISO 10651-4:2002, the inspiratory resistance shall not exceed 5 cm H_2O below atmospheric pressure.
Revivator, Ambu and Mercury Medical resuscitators have values much lower than the admissible or in the case of Ambu Spur II _(adult and pediatric resuscitators) which have an inspiratory resistance of 5 cm H_20 at 50 l/min

The design of the resuscitator should be such that it is possible for the patient to breathe spontaneously without excessive subatmospheric pressure when the resuscitator is applied to the patient's airway.
Since Revivator resuscitators have low inspiratory resistance, they let patients to breathe better spontaneously than predicate devices.

Patient and expiratory connector

The patient and expiratory connectors are described in ISO 10651-4:2002.
Both Revivator and Ambu resuscitators are in conformity with this standard:

- patient connectors : 22/15 mm
- expiratory connectors: 30 mm male

Mercury Medical don not include information on connectors in the labeling.

Applications

2.1. Controlled ventilation with ambient air: without reservoir nor connection to the oxygen source, at 21% of O_2 concentration is obtained.
2.2. Controlled ventilation with supplemental oxygen with or without reservoir: the use of additional O_2 allows to obtain an adjustable concentration from 21 up to 100%,

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according to the flow of the O_2 source. This is the recommended practise by all the actual resuscitation guidelines. The use of the reservoir allows a saving of O_2 upper than 50%.

Both applications are available for all resuscitators.

Ambu resuscitators also include the ventilation with a face mask and the oxygen administration (instructions for use, point 5)

Mercury medical resuscitators consider these applications in several sentences included in its instructions:

Precautions- 3- If used with supplemental oxygen (...)

Directions for use-6- when a bag reservoir is being used (...)

In addition the ISO 10651-4 allows an attachment to reach high concentration of oxygen

3. Other recommended configurations

3.1.System of fixation of the mask to the head (head strap wring): It is recommended during the anesthesia, prolonged controlled ventilation, spontaneous ventilation with O_2 inhalation and during the transport of the patient; thanks to the design of the provided masks, a slight pressure is enough to obtain a perfect seal with the face.

Although the face mask provides a perfect seal with the face mask, it is available a head strap wring.

This configuration is not included in the predicate devices. This is a useful accessory for the rescuer in order to have a system of fixation of the mask to the head specially when patients have to be transported.

3.2.Ventilation with PEEP: The expiratory port is a 30 mm conical male apt for the connection of any standardized PEEP valve.

Ambu reusable resuscitators also include an expiratory connector for PEEP valve (direction for use- point 3.- specifications and point 12- accessories)

Mercury medical resuscitators consider this configuration their directions of use-point 9 : "The patient valve features a built-in PEEP Adapter Port (...)"

In addition ISO 10651-4 allows an expiratory port of 30 mm.

3.3.Airway pressure manometer: By means of Fig. 7 assembly the air-way pressure; this control is very important when the patient is ventilated with the pressure-limiting valve

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blocked, or when it is coupled a PEEP valve or a system of breathed anesthetic gas evacuation.

A pressure gauge is also available for Ambu resuscitators. Direction for use, point 5.1 : " A pressure gauge can be connected to the tube connector on the side of the patient valve for monitoring ventilation pressure"

Mercury medical resuscitators consider this configuration their directions of use-point 4 and 9 : "The use of an airway pressure manometer is recommended (...)" and " When adjusting the Mercury Medical PEEP Valve, connect a manometer in line (...)"

Bag refill valve connectors

According to ISO 10651-4:2002, it shall be a 32 mm female conical connector.
The connector of Revivator resuscitators is a 32 mm female connector and the predicates are also in conformity with ISO 10651-4:2002/ ISO 8382, so they shall be 32 mm female conical connector, although it is not included in their labelling. The standards ISO10651-4/ISO8382 do not require this information to be included in the labelling.

Dismantling and reassembly

All resuscitators intended to be reused and dismantled by the user includes in their labelling a functional test of operation to be carried out after reassembly

Patient Valve function after contamination with vomitus

All resuscitators are in conformity with ISO 10651-4/ISO8382.
The standards ISO10651-4/ISO8382 do not require this information to be included in the labelling.

Drop test

All resuscitators are in conformity with ISO 10651-4/ISO8382.
The standards ISO10651-4/ISO8382 do not require this information to be included in the labelling.

Immersion in water

All resuscitators are in conformity with ISO 10651-4/ISO8382.
The standards ISO10651-4/ISO8382 do not require this information to be included in the labelling.

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Supplementary oxygen and delivered concentration

Resuscitators shall deliver a minimum oxygen concentration of at least 35% (V/V) when connected to an oxygen source supplying not more than 15l/min and shall be capable of delivering at least 85%(V/V). the 85% may be accomplished with the use of an attachment. The manufacturer shall state the range of concentrations at representative flows.

Considering the test conditions (C20, R20, 12 bpm and 600 mL), all resuscitators deliver the minimum oxygen concentration.

Expiratory resistance

According to ISO 10651-4:2002, the expiratory resistance shall not exceed 5 cm H_2O

Revivator, Ambu and Mercury Medical resuscitators have values much lower than the admissible value.

Moreover, to facilitate exhalation, expiratory resistance should be minimized. Since Revivator resuscitators have lower expiratory resistance than predicate devices, Revivator resuscitators facilitate a better exhalation comparing with the predicate devices

Inspiratory resistance

According to ISO 10651-4:2002, the inspiratory resistance shall not exceed 5 cm H_2O below atmospheric pressure.
Revivator, Ambu and Mercury Medical resuscitators have values much lower than the admissible or in the case of Ambu Spur II _(adult and pediatric resuscitators) which have an inspiratory resistance of 5 cm H_20 at 50 l/min

The design of the resuscitator should be such that it is possible for the patient to breathe spontaneously without excessive subatmospheric pressure when the resuscitator is applied to the patient's airway.
Since Revivator resuscitators have low inspiratory resistance, they let patients to breathe better spontaneously than predicate devices.

Patient valve malfunction

All resuscitators are in conformity with ISO 10651-4/ISO8382.

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5. "510(k) SUMMARY"

The standards ISO10651-4/ISO8382 requires to include in the instructions for use the value of end-expiratory pressure generated by the resuscitator in normal use, if greater than 0.2 kPa. In addition the pressure gradient shall be lower than 0.6 kPa

There is not an increase in the pressure gradient at the end of expiration at 30 L/min in Revivator resuscitators.

As the value of the end –expiratory pressure generated in not included in the instructions of the predicate devices, it is expected to be lower than 0.2 kPa. Therefore predicate devices are also in conformity with the standard.

Apparatus deadspace. Dead space of patient valve

The dead space for Revivator is lower than 7 mL. The predicate devices has a dead space lower between 5 and 7 mL.
The differences of the dead space between Revivator, Ambu and Mercury Medical do not raise safety concerns, since according to the ISO 10651-4:2002 the apparatus dead space shall not exceed 5 mL +10 % of the minimum delivered volume.

According to Table 1, ISO 10651-4:2002	Deadspace
B <5 , Vdel=20 mL	<7 mL
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10<B<40, Vdel=15xB mL	
B>40, Vdel=600mL	65 mL

Therefore, values lower than 7 ml of dead space for Revivator resuscitators are completely admissible and it does not affect the safety and effectiveness of the resuscitators.

Maximum tidal volume

According to ISO the maximum tidal volume shall be at least:

- 150 mL for resuscitators for people with a body weight lower than 10 kg
- 450 mL for resuscitators for people with a body weight between 10 and 40 kg
- 600 mL for resuscitators for people with a body weigh higher than 40 kg

Therefore, all resuscitators are according to this standard.

Pressure-limiting valve

The ISO 10651-4:2002 says that all resuscitators intended for use with people with a body weight lower than 10 kg shall have a pressure limitation system.

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The pressure shall not be higher than 4.5 kPa.

Revivator resuscitators for child and infants has a pressure limiting valve at 4.5 kPa
Ambu silicone resuscitators and Ambu Spur II for child and infant has also a pressure limiting valve at 4.0 kPa.
Mercury medical resuscitators (child and infant models) have also a pressure-limiting valve at 4.0 ± 0.5 kPa
Both 4.5 kPa and 4.0 kPa are admissible according to the standard. So they can be considered safe and equivalent.

Revivator resuscitaros for adults also include a pressure limiting valve at 6 kPa and Ambu Spur II has also available a pressure limiting valve at 4,0 kPa. Mercury medical resuscitators have also an optional pressure limiting valve for small adults
ISO 10651-4:2002 considers this option for resuscitators for people with a body weight higher than 10 kg. The pressure shall be lower than 6 kPa. Therefore both resuscitators meet ISO 10651-4:2002 and they can be considered as safe devices.

Storage conditions

The resuscitator shall after storage at temperatures of –40°C and +60°C and at any relative humidity between 40% and 95% meet the general and specific requirements specified in the standard.
All resuscitators meet these storage conditions. In addition Revivator and Ambu reusable resuscitators can be also storaged at 70°C because of the materials have been selected to be reused and sterilized.

Operating conditions

Resuscitators shall meet the requirements specified in the standard throughout the temperature range from –18°C to +50°C and a humidity range from 40% to 95% r.h.

All resuscitators meet these operating conditions. In addition Revivator and Ambu reusable resuscitators can be also used at -20°C.

CONCLUSIONS

Considering the similarities and that the small differences are justified by the standard ISO 10651-4:2002, REVIVATOR resuscitators can be considered equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Ana Maria Romero
Quality Assurance
Hersill, S. L.
Puerto De Navacerrada, 3
Mostoles (Madrid)
Spain 28935

SEP 17 2010

Re: K094003
Trade/Device Name: Revivator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: September 10, 2010
Received: September 10, 2010

Dear Ms. Romero:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. INDICATIONS FOR USE STATEMENT K094003

Indications for Use

SEP 17 2010

510(k) Number (if known): _____

Device Name: REVIVATOR

Indications for Use:

The Revivator resuscitator is intended for pulmonary resuscitation.

The adult resuscitator is for people with a body weight of more than 30 kg (66 lbs)

The child resuscitator is for children with a body weight between 7 and 30 kg (15-66 lbs)

The infant resuscitator is for infants with a body weight up to 7 kg (15 lbs)

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K094003