August 26, 2021

Xiamen Compower Medical Tech. Co., Ltd.
℅ Mingzi Hussey
Regulatory Consultant
Zi-medical, Inc.
93 Springs Rd
Bedford, Massachusetts 01730

Re: K210288
Trade/Device Name: Disposable Manual Resuscitator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: May 11, 2021
Received: July 29, 2021

Dear Mingzi Hussey:

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/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,

For Brandon Blakely, Ph.D.
*Acting* Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K210288

Device Name
Disposable Manual Resuscitator

Indications for Use *(Describe)*
Single patient use manual resuscitator for use in hospital, transport, emergency, and post-hospital care to temporary ventilate a patient for the given body mass ranges of:
Infant: less than or equal to 10 kg
Child: less than or equal to 23 kg
Adult: greater than 23 kg

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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006 510(k) Summary

## GENERAL INFORMATION

### 1 Type of Submission

Traditional 510(k) Submission

Date Prepared: 08/26/2021

### 2 Submitter


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E-mail mingzi@zi-medical.com


### 3 Establishment Registration Number

3008261717

### 4 Common Name or Classification Name

Manual emergency ventilator (Resuscitator) (CFR 868.5915, Product Code BTM)

### 5 Trade Name

Disposable Manual Resuscitator

### 6 Device Classification

This is a Class II device

### 7 Reason for Premarket Notification

Introducing a (finished) device into commercial distribution (marketing) in the U.S. for the first time.

## 8 Legally Marketed Predicate Device

Foremount Disposable PVC Resuscitator Model A1

K170663 Code BTM

## 9 Predicate Device Company

Foremount Enterprise Co., Ltd.

## 10 Device Description

Disposable manual resuscitator is disposable, medical device, which temporarily augment ventilation in patients during ventilatory insufficiency or ventilator failure. Disposable manual resuscitator uses a duck-bill valve in the non-rebreathing valve assembly, attaches the non-rebreathing valve directly onto the resuscitation bag and includes an oxygen enrichment (reservoir) system. Disposable manual resuscitator may be used in hospital, transport, emergency, and post hospital care to temporary ventilate a patient.

Disposable manual resuscitator is for single patient used. It comprises of mask, oxygen tube, reservoir bag and resuscitator bag. It is used to temporary ventilate a patient for the given body mass ranges of:

- Infant - Less than or equal to 10 kg
- Child - less than or equal to 23 kg
- Adult - Greater than 23 kg.

Models:

There are three device models subject to this 510(k) premarket notification including:

- NPVC-001/RTMA--Adult disposable manual resuscitator
- NPVC-002/RTMA--Child disposable manual resuscitator
- NPVC-003/RTMA1--Infant disposable manual resuscitator

The ventilation bags are available in three sizes based upon the intended patient population. They are provided with three different sizes of masks.

## 11 Intended Use Statement

Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:
Infant: less than or equal to 10Kg, Child: less than or equal to 23 Kg, Adult: greater than 23 Kg.

## 12 Required Components

Mask
Resuscitator bag (including intake valve and patient connector)
Reservoir bag
Oxygen tube

## 13 Summary Table of Comparison

Table 1 outlines the predicate device functions comparing with Compower Disposable Manual Resuscitator

Comparison with Foremount Disposable PVC Resuscitator (K170663)

| | **Foremount Disposable PVC Resuscitator, Model A1 (K170663)** | **Disposable Manual Resuscitator** | **Substantial Equivalence Discussion** |
|---|---|---|---|
| **Indication for Use** | Single patient use manual resuscitatorfor use hospital, transport, emergency,and post hospital care to temporary ventilate a patient for the given body mass ranges of:<br>Infant: ≤10kg,<br>Child: ≤23kg,<br>Adult: >23kg. | Single patient use manual resuscitator foruse hospital, transport, emergency, and post hospital care to temporary ventilate apatient for the given body mass ranges of:<br>Infant: ≤10kg,<br>Child: ≤23kg,<br>Adult: >23kg. | Same |
| **Target population** | Infant: ≤10kg,<br>Child: ≤23kg,<br>Adult: >23kg. | Infant: ≤10kg,<br>Child: ≤23kg,<br>Adult: >23kg. | Same |
| **Classification** | BTM<br>CFR 868.5915 Ventilator, Emergency,Manual (Resuscitator) | BTM<br>CFR 868.5915 Ventilator, Emergency,Manual (Resuscitator) | Same |
| **Component** | 1. Self-inflating bag<br>2. Intake valves<br>3. Oxygen collection bag<br>4. Oxygen tubing<br>5. Patient connector<br>6. Face mask<br>7. Pressure limiting valve<br>8.Options-Pop-off, PEEP valve,Pressure manometer | 1. Mask<br>2. Resuscitator bag(Including intake valveand patient connector)<br>3. Reservoir bag<br>4. Oxygen tube<br>5. Pressure limiting valve | Different |
| **Pressure Limiting Valve** | Pressure limiting valve comprised of spring, pressure limiting valve cover, pressure limiting valve core and spring pad | Pressure limiting valve comprised of spring, pressure limiting valve cover, pressure limiting valve core and spring pad | Same |
| **Environment of Use** | Hospital, Transport, emergency and posthospital care | Hospital, Transport, emergency and posthospital care | Same |
| **Principal of operation** | The patient valve contains a duckbill valve that directs air from compression of the ventilation bag through a patient connector into the patient airway duringinspiration and directs the patient expired air out to the atmosphere when the ventilation bag is released during exhalation. If the patient valve incorporates a pop off | The patient valve contains a duckbill valve that directs air from compression of the ventilation bag through a patient connectorinto the patient airway during inspiration and directs the patient expired air out to the atmosphere when the ventilation bag isreleased during exhalation. If the patient valve incorporates a pressure limiting | Same |

| | | | |
|---|---|---|---|
| | valve (40 cmH2Ofor infant and child and 60 cmH2O for adult), excessive pressure will be exhausted to atmosphere to prevent pressure trauma. | valve (40 cmH2O for infant and child and 60 cmH2O for adult), excessive pressure will be exhausted to atmosphere to prevent pressure trauma. | |
| **Patient Connector** | 15ID/22OD | 15ID/22OD | Same |
| **Pressure Limit** | 40cmH2O<br>60cmH2O | 40cmH2O<br>60cmH2O | Same |
| **Duration of use** | Single patient, disposable<24 hours | Single patient, disposable<24 hours<br>Normal use < 1 hr | Same |
| **Dimensions** | Adult: 445x190mm<br>Child: 350x177mm<br>Infant: 325x165mm | Adult: 212x131mm<br>Child: 177x113mm<br>Infant: 126x93mm | Different |
| **Intake valves** | External 2 valve design<br>Integrated design | External 2 valve design<br>Integrated design | Same |
| **Can provide supplemental oxygen** | Yes | Yes | Same |
| **Material** | PVC, Polycarbonate, Silicone | PVC, Polycarbonate, Silicone | Same |
| **Energy used/ delivered** | N/A | N/A | Same |
| **Performance Data** | | | |
| Ventilation Bag Volume | Adult: 1700 ml<br>Child: 500ml<br>Infant: 320ml | Adult: 1500ml<br>Child: 1000ml<br>Infant: 520ml | Different |
| Oxygen collection Bag Volume | Adult: 1000ml<br>Child: 1000ml<br>Infant: 600ml | Adult: 2000ml<br>Child: 1600ml<br>Infant：1600ml | Different |
| Max Delivered Volume (single hand) | Adult: 650 ml<br>Child: 370 ml<br>Infant: 180 ml | Adult: 500 ml<br>Child: 345 ml<br>Infant: 150 ml | Different |
| Dead Space | ~3.8ml for all sizes | Adult: 7.3<br>Child: 7.1<br>Infant: 6.8 | Different |
| Expiratory resistance<br>Adult@50 lpm<br>Child @5 lpm<br>Infant@5 lpm | Adult: 2.8H2O Child: 0.5cmH2OInfant: 0.5cmH2O | Adult:1.39cmH2O<br>Child:1.30cmH2O<br>Infant:0.04cmH2O | Different |
| Inspiratory resistance<br>Adult@50 lpm<br>Child @5 lpm<br>Infant@5 lpm | Adult: 3cm H2O Child: 0.5cm H2OInfant: 0.5cmH2O | Adult:0.98cmH2O<br>Child:0.98 cmH2O<br>Infant: 0.04cmH2O | Different |
| Supplemental Oxygen% at different flow rates and Tidal Volumes (VT)— | 2L/min 5L/min 10L/min<br>70ml/ 20bpm 90% 98% 98%<br>70ml/ 30bpm 87% 99% 98% | 2L/min 5L/min 10L/min<br>70ml/ 20bpm 76% 82% 83%<br>70ml/ 30bpm 80% 87% 90% | Different |

<table>
<tr><td>Infant</td><td></td><td></td><td></td></tr>
<tr><td>Supplemental Oxygen% at different flow rates and Tidal Volumes (VT)—Child</td><td><table><tr><td></td><td>2L/min</td><td>5L/min</td><td>10L/min</td></tr><tr><td>200ml/ 20bpm</td><td>57%</td><td>99%</td><td>98%</td></tr><tr><td>300ml/ 30bpm</td><td>39%</td><td>66%</td><td>98%</td></tr></table></td><td><table><tr><td></td><td>2L/min</td><td>5L/min</td><td>10L/min</td></tr><tr><td>200ml/ 20bpm</td><td>61%</td><td>96%</td><td>96%</td></tr><tr><td>300ml/ 30bpm</td><td>36%</td><td>57%</td><td>98%</td></tr></table></td><td>Different</td></tr>
<tr><td>Supplemental Oxygen% at different flow rates and Tidal Volumes (VT)--Adult</td><td><table><tr><td></td><td>5L/min</td><td>10L/min</td><td>15L/min</td></tr><tr><td>600ml/ 12 bpm</td><td>83%</td><td>99%</td><td>98%</td></tr><tr><td>750ml/ 12bpm</td><td>57%</td><td>99%</td><td>99%</td></tr><tr><td>1000ml/ 12bpm</td><td>40%</td><td>60%</td><td>70%</td></tr></table></td><td><table><tr><td></td><td>5L/min</td><td>10L/min</td><td>15L/min</td></tr><tr><td>600ml/ 12 bpm</td><td>72%</td><td>99%</td><td>99%</td></tr><tr><td>750ml/ 12bpm</td><td>57%</td><td>95%</td><td>99%</td></tr><tr><td>1000ml /12bpm</td><td>/</td><td>/</td><td>/</td></tr></table></td><td>Different</td></tr>
<tr><td>Operating temperature</td><td>-18°C to 50°C</td><td>-18°C to 50°C</td><td>Same</td></tr>
<tr><td>Storage Temperature</td><td>-40°C to 60°C</td><td>-40°C to 60°C</td><td>Same</td></tr>
<tr><td>Sterile or Non-sterile</td><td>Non-sterile</td><td>Non-sterile</td><td>Same</td></tr>
<tr><td>Single patient use or Reuse</td><td>Single patient use</td><td>Single patient use</td><td>Same</td></tr>
<tr><td>Connectors</td><td>Non-Rebreathing Valve connector, Bagconnector are conform with ISO 5356-1:2015.</td><td>Non-Rebreathing Valve connector, Bagconnector are conform with ISO 5356-1:2015.</td><td>Same</td></tr>
<tr><td>Trained users</td><td>The product should only be used bypersons trained in resuscitation.<br>Use of product is well known to trainedusers.</td><td>This product must be used by persons who are trained in techniques of pulmonary resuscitation. Use of product is well known to trained users.</td><td>Same</td></tr>
<tr><td>Rx only or OTC only</td><td>RX only</td><td>RX only</td><td>Same</td></tr>
<tr><td>Compatibility with other devices</td><td>The device can compatibility with otherdevices, e.g. face mask, PEEP Valve, Manometer, Filter and Oropharyngeal airways when used.</td><td>The device can compatibility with other devices, e.g. oropharyngeal airways. Alsoit can be used separately.</td><td>Same</td></tr>
<tr><td>Where used</td><td>Emergency situations in hospital, transport, emergency, and post hospitalcare.</td><td>Emergency situations in hospital, transport, emergency, and post hospitalcare.</td><td>Same</td></tr>
</table>

| | | | |
|---|---|---|---|
| **Standards met** | ISO 5356-1:2015<br>ISO 10651-4:2002<br>ISO 10993-1:2018<br>ISO 10993-5:2009<br>ISO 10993-10:2013<br>ISO 10993-11:2017 | ISO 5356-1:2015<br>ISO 10651-4:2002<br>ISO 10993-5:2009<br>ISO 10993-10:2013<br>ISO 10993-11:2017<br>ISO 18562-1:2017<br>ISO 18562-2:2017<br>ISO 18562-3:2017 | |
| **Electrical, thermal or radiation safety** | N/A | N/A | Same |
| **Shelf life** | 5 years | 3 years | Different |
| **Biocompatibility** | Externally communicating, tissue and Surface Contact, skin Limited durationof use (<24h)<br>Testing – Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Gas emission VOC, PM2.5, Inorganic gases(Ozone, CO, CO2) | Externally communicating, tissue and Surface Contact, skin Limited duration ofuse (<24h)<br>Testing – Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Gas emission VOC, PM2.5, Inorganic gases(Ozone, CO, CO2) | Same |

Table 1 Comparison Table

## 14 Summary of Device Testing

The following practices were followed and monitored for development of the Disposable Manual Resuscitators:

- The device was developed and tested according to GMP Standard Operating Procedures for Medical Devices.
- Risk Analysis of the device was performed according to ISO 14971.
- Human Factors/Usability Engineering validation according to IEC 62366-1 demonstrated the safety and efficacy of the device.
- Biocompatibility was evaluated in accordance with ISO 10993-1 and ISO 18562-1.
- Biocompatibility tests was conducted according to ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 18562-2 and ISO 18562-3.
- Performance test is conducted according to ISO 10651-4 and ISO 5356-1.
- Shelf life test is conducted according to ASTM F1980.

## 15 Comparison Summary

The Disposable Manual Resuscitators are viewed as substantially equivalent to the predicate device because:

Indications for use

The proposed indications for use are the same as predicate.

Patient Population

The patient population is the same as predicate.

Components
Similar as the predicate device without peep valve and pressure manometer. Those two items are optional accessories which won't impact product safety and effectiveness.

Environment of Use
The environment of use is the same as predicate.

Technological Characteristics
The design and principle of operation is similar to the predicate. The configuration and functionality is similar. The differences in specification, e.g. maximum delivered volume, dead space and ventilation bag volume do not raise new safety or effectiveness concerns related to substantial equivalence as ISO 10651-4 and ISO 5356-1 specifies the minimum requirements and the subject device and the predicate both meet the minimum requirements as listed in the standard. The operating principle of the Compower Resuscitator is the same as the identified predicate devices.

Shelf life
Shelf life testing is conducted based on ASTM F1980:2016 and result is passed. The shorter of shelf life does not raise any safety or efficacy issue.

Biocompatibility
Biocompatibility test conducted for Cytotoxicity, sensitization, irritation and acute systemic toxicity study, emissions of VOC and aldehydes, gas emission of CO, CO2, Ozone, PM2.5, PM10 has demonstrate the substantial equivalence.

No new issues of biocompatibility raised with regard to the Disposable Manual Resuscitator.

Non-clinical data
Performance test is conducted according to ISO 10651-4 and ISO 5356-1 for Appearance, dimension measurement, expiratory resistance, inspiratory resistance, patient valve malfunction, max delivered volume (single hand), pressure limitation, dead space, supplementary oxygen and delivered oxygen concentration, patient valve function after contamination with vomitus, drop test, immersion in water, storage and operation conditions, method of test for strength nipple to demonstrate the substantial equivalence.

Risk management report according to ISO14971:2019 and Usability test according to IEC 62366-1:2015 has been conducted and no new issues raised.

## 16 Conclusion

There are no differences between the proposed device and the predicates, which raise different safety or effectiveness concerns. Based on the device design, risk assessment and non-clinical tests data generated from biocompatibility test and performance test, we can conclude that the proposed device and accessory components can be considered substantially equivalent. Based upon the testing the sponsor has demonstrated the equivalence of the subject device compared to the legally marketed predicate device.