Xiamen Compower Medical Tech. Co. Ltd.
% Lynn Jensen
Principal Medical Research Manager, Regulatory Affairs
NAMSA
400 Highway 169 South Suite 500
Minneapolis, Minnesota 55426

Re: K171961

Trade/Device Name: CPR Mask with Oxygen Port, CPR Mask without Oxygen Port, Infant CPR Mask without Oxygen Port, Non-Rebreathing Valve (15mmOD), Non-Rebreathing Valve (18.5mm)
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: Class II
Product Code: CBP
Dated: October 18, 2017
Received: October 19, 2017

Dear Lynn Jensen:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

Tara A. Ryan -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
Indications for Use

Device Name
CPR Mask with Oxygen Port

Indications for Use (Describe)
The CPR Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask with Oxygen Port is intended for prescription use.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)
K171961

Device Name
CPR Mask without Oxygen Port

Indications for Use (Describe)
The CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask without Oxygen Port is intended for over-the-counter use.

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)

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PRASstaff@fda.hhs.gov

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Indications for Use

Device Name
Infant CPR Mask without Oxygen Port

Indications for Use (Describe)
The Infant CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The Infant CPR Mask is indicated for use on infants with body weight up to 10 kg (22 lbs). The Infant CPR Mask is intended for over-the-counter use.

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)

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FORM FDA 3881 (7/17)
Indications for Use

510(k) Number (if known)
K171961

Device Name
Non-Rebreathing Valve (15mmOD)

Indications for Use (Describe)
The Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. It is intended for over-the-counter use.

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)

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Indications for Use

510(k) Number (if known)
K171961

Device Name
Non-Rebreathing Valve (18.5mm)

Indications for Use (Describe)
The Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. It is intended for over-the-counter use.

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)

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In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER NAME
Xiamen Compower Medical Tech Co Ltd.
3F, No.16-1 Xianghong Road, Xiang'an Torch
Industrial Zone, Xiamen, 361101, China
Phone: +86-13306000572
Primary Contact Person: Lynn Jensen – NAMSA Regulatory Affairs
Phone: 651-206-6530
Date Submitted: October 18, 2017

II. DEVICE
Name of Device: CPR Mask with Oxygen Port
   CPR Mask without Oxygen Port
   Infant CPR Mask without Oxygen Port
   Non-Rebreathing Valve (15mmOD)
   Non-Rebreathing Valve (18.5mm)
Common/Usual Names: CPR Mask / Non-Rebreathing Valve
Classification Name: Non-Rebreathing Valve
Regulation Class: II
Regulation Number: 868.5870
Product Code: CBP
Panel: Anesthesiology

III. PREDICATE/REFERENCE DEVICES
- Kyoling CPR Mask with Oxygen Port (Prescription Use) K142764 – Decision Date: July 9, 2015
- Kyoling CPR Mask without Oxygen Port (Over the Counter Use) K142764 - Decision Date: July 9, 2015
- Engineered Medical Systems Child/Infant Facemask with Non-Rebreathing Valve (Over the Counter Use) K983919 – Decision Date: April 7, 1999 (Primary Predicate)
- Laerdal Paediatric Pocket Mask (Model 820050) K023805 – Decision Date: February 11, 2003 (Reference Device)
- Seal Rite™ Non-Rebreathing Valve (Over the Counter Use) K152521 – Decision Date: June 3, 2016

IV. DEVICE DESCRIPTION
Compower Emergency CPR masks with non-rebreathing valves are designed to assist in providing immediate life support to health emergency victims requiring oxygen support and cardiopulmonary resuscitation rescue techniques. The devices subject to this 510(k) include the following:
CPR Mask with Oxygen Port
The CPR Mask with Oxygen Port is comprised of an air cushion, foldable mask cover with oxygen port, a non-rebreathing valve and an elastic head strap. The air cushion is designed to promote an airtight seal with the patient’s face and the oxygen port allows for the delivery of supplemental oxygen to the patient. The mask is constructed of transparent polyvinyl chloride and is fitted with a non-rebreathing valve designed for resuscitation and providing a physical barrier between the rescuer and patient. The CPR Mask with Oxygen Port is indicated for prescription use. The device is provided non-sterile and is intended for single use only.

CPR Mask without Oxygen Port
The CPR Mask without Oxygen Port is comprised of an air cushion, foldable mask cover, a non-rebreathing valve and an elastic head strap. The air cushion is designed to promote an airtight seal with the patient’s face during use. The mask is constructed of transparent polyvinyl chloride and is fitted with a non-rebreathing valve designed for resuscitation and to provide a physical barrier between the rescuer and patient. The CPR Mask without Oxygen Port is indicated for over the counter use. The device is provided non-sterile and is intended for single use only.

Infant CPR Mask without Oxygen Port
The Infant CPR Mask is comprised of an air cushion, mask cover and non-rebreathing valve. The air cushion is designed to promote an airtight seal with the patient’s face during use. The mask is constructed of transparent polyvinyl chloride and is fitted with a non-rebreathing valve designed for resuscitation and to provide a physical barrier between the rescuer and patient. The Infant CPR Mask is indicated for over the counter use. The device is provided non-sterile and is intended for single use only.

Non-Rebreathing Valve
The Non-Rebreathing Valve is a non-sterile, single-use device. The device is designed with a rigid styrene-butadiene copolymer housing, a silicone valve plate and polypropylene filter. The valve is compatible for use with 22mm connectors used in standard ventilation masks. During use, the rescuer blows air into the non-rebreathing valve that is filtered and breathed by the patient. The patient’s expiratory breath is directed through an open hole on the side of the valve and is prevented from flowing back to the rescuer by the silicone valve. The Non-Rebreathing Valve is designed with 15mmOD and 18.5mm ports and is indicated for over the counter use.

V. INDICATION FOR USE
CPR Mask with Oxygen Port
The CPR Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask with Oxygen Port is intended for prescription use.
CPR Mask without Oxygen Port
The CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask without Oxygen Port is intended for over-the-counter use.

Infant CPR Mask without Oxygen Port
The Infant CPR Mask without Oxygen Port is designed to provide immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The Infant CPR mask is indicated for use on infants with body weight up to 10 kg (22 lbs). The Infant CPR Mask is intended for over-the-counter use.

Non-Rebreathing Valve (15mmOD)
The Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. It is intended for over-the-counter use.

Non-Rebreathing Valve (18.5mm)
The Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. It is intended for over-the-counter use.

VI. SUBSTANTIAL EQUIVALENCE
The following information supports the substantial equivalence of Xiamen Compower Medical Tech Co Ltd devices described in this premarket notification as compared to predicate and reference devices cleared for marketing.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xiamen Compower Medical Tech Co Ltd</td>
<td>Hangzhou Jinlin Medical Appliances Co. Ltd</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Compower CPR Mask</th>
<th>KYOLING CPR Mask</th>
</tr>
</thead>
<tbody>
<tr>
<td>K171961</td>
<td>K142764</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code</th>
<th>CBP</th>
<th>CBP</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>FDA Classification</th>
<th>868.5870</th>
<th>868.5870</th>
</tr>
</thead>
</table>

| Indications for Use - With Oxygen Port | The CPR Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation | Same |
## Indications for Use - Without Oxygen Port

The CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask without Oxygen Port is intended for over-the-counter use.

## How Provided

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mask (with or without oxygen port), non-rebreathing valve and head strap.</td>
<td>Mask (with or without oxygen port), universal breathing tube, non-rebreathing valve with filter and head strap.</td>
</tr>
<tr>
<td>Non Sterile</td>
<td>Non Sterile</td>
</tr>
</tbody>
</table>

## Inspiratory Resistance Specification ≤0.5 kPa at 50 L/min

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.40 – 0.49 kPa at 50 L/min</td>
<td>0.30 – 0.31 kPa at 50 L/min</td>
</tr>
</tbody>
</table>

## Expiratory Resistance Specification ≤0.5 kPa at 50 L/min

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.20 – 0.30 kPa at 50 L/min</td>
<td>0.31 – 0.32 kPa at 50 L/min</td>
</tr>
</tbody>
</table>

## Device Materials

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face Mask: PVC</td>
<td>Face Mask: PVC</td>
</tr>
<tr>
<td>Valve Housing: Rigid styrene-butadiene copolymer (K-resin)</td>
<td>Valve Housing: Rigid plastic (K-resin)</td>
</tr>
<tr>
<td>Valve Plate: Silicone</td>
<td>Valve Plate: Silicone</td>
</tr>
<tr>
<td>Filter: Polypropylene</td>
<td>Filter: Not Known</td>
</tr>
</tbody>
</table>

## Dimensions

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>Kyoling CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length: 124 mm</td>
<td>Length: 122 mm</td>
</tr>
<tr>
<td>Width: 99 mm</td>
<td>Width: 99 mm</td>
</tr>
</tbody>
</table>

## Standards Used to Support Design and Performance Testing

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 5356-1: Anaesthetic and respiratory equipment- Conical connectors-Part 1: Cones and Sockets</td>
<td>Same</td>
</tr>
<tr>
<td>AS 4259-1995-Ancillary devices for expired air resuscitation</td>
<td></td>
</tr>
</tbody>
</table>

## Biocompatibility Testing Conducted

<table>
<thead>
<tr>
<th>Compower CPR Mask Subject Device</th>
<th>KYOLING CPR Mask Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 10993-5 - Cytotoxicity</td>
<td>Same</td>
</tr>
<tr>
<td>ISO 10993-10 - Sensitization</td>
<td></td>
</tr>
</tbody>
</table>
There were no significant differences noted between the Compower CPR Mask with and without Oxygen Port and the corresponding predicate devices that would raise new issues of safety and efficacy of the Compower CPR masks for their intended use. The subject devices have the same indications for use and the same or similar technological characteristics, principles of operation, components, material composition, performance compliance and biological safety compliance as the predicate devices.

The inspiratory resistance and expiratory resistance values are not the same between the subject and predicate devices. The differences can be explained due to slightly different design features of the non-rebreathing valves. These differences do not raise new issues of safety and efficacy as inspiratory and expiratory requirements of AS 4259 were met by all the subject and predicate devices.

The Compower CPR Masks with and without Oxygen Port are substantially equivalent to the predicate Kyoling CPR Masks with and without Oxygen Port.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Xiamen Compower Medical Tech Co LTD</th>
<th>Engineered Medical Systems EMS</th>
<th>Laerdal Medical A/S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>Compower Infant CPR Mask Subject Device</td>
<td>EMS CPR Mask Primary Predicate</td>
<td>Laerdal Paediatric Pocket Mask</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>K171961</td>
<td>K983919</td>
<td>K023805</td>
</tr>
<tr>
<td>Product Code</td>
<td>CBP</td>
<td>CBP</td>
<td>CBP</td>
</tr>
<tr>
<td>FDA Regulatory Classification</td>
<td>868.5870</td>
<td>868.5870</td>
<td>868.5870</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Infant CPR Mask is designed to provide immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The Infant CPR mask is indicated for</td>
<td>Indicated to provide assisted ventilation to someone requiring assisted ventilation, breathing or resuscitation, by use of a mouth to mask method. Patient population is</td>
<td>Laerdal Paediatric Pocket Mask is a device designed for mouth-to-mask ventilation of a non-breathing child or infant.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comparison of Subject and Predicate/Reference Infant CPR Mask</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
</tr>
<tr>
<td><strong>Device Name</strong></td>
</tr>
<tr>
<td><strong>510(k) Number</strong></td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
</tr>
<tr>
<td><strong>FDA Regulatory Classification</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td><strong>use on infants with body weight up to 10 kg (22 lbs). The Infant CPR Mask is intended for over-the-counter use.</strong></td>
</tr>
<tr>
<td><strong>Inspiratory Resistance Specification ≤0.5 kPa at 50 L/min</strong></td>
</tr>
<tr>
<td><strong>Exspiratory Resistance Specification ≤0.5 kPa at 50 L/min</strong></td>
</tr>
<tr>
<td><strong>Design</strong></td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
</tr>
<tr>
<td><strong>Dead Space (AS 4259-1995 Specification ≤ 120 ml)</strong></td>
</tr>
</tbody>
</table>
The Compower Infant CPR Mask (subject device) and the EMS Child/Infant CPR mask without oxygen port (primary predicate device) are transparent molded CPR masks with non-rebreathing valves intended for over the counter use. The Compower Infant CPR Mask has the same intended use as the EMS Child/Infant CPR Mask but specifies a more limited indication for use with infants up to 10 kg.

The Compower Infant CPR Mask with Non-Rebreathing Valve has the same intended use, same or similar materials, technological characteristics, principles of operation and components as compared to the primary predicate EMS Child/Infant CPR Mask with Non-Rebreathing Valve. The subject device also demonstrates similar performance characteristics to the Laerdal Pediatric Pocket Mask reference device.

The inspiratory resistance and expiratory resistance values are not the same between the subject and reference device. The differences can be explained due to slightly different design features of the non-rebreathing valves. These differences do not raise new issues of safety and efficacy as inspiratory and expiratory requirements of AS 4259 were met by the subject and reference device.

There were no significant differences noted between the Compower Infant CPR Mask with Non-Rebreathing Valve and the EMS Child/Infant CPR Mask with Non-
Rebreathing Valve that raise new issues of safety and efficacy of the subject device for its intended use. The Compower Infant CPR Mask with Non-Rebreathing Valve is substantially equivalent to the EMS Child/Infant CPR mask with Non-Rebreathing Valve.

Comparison of Subject and Predicate Non-Rebreathing Valve

<table>
<thead>
<tr>
<th></th>
<th>Compower Non-Rebreathing Valve</th>
<th>Seal Rite™ Non-Rebreathing Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Xiamen Compower Medical Tech Co Ltd</td>
<td>The Lifeguard Store, Inc.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Compower Non-Rebreathing Valve</td>
<td>Seal Rite™ Non-Rebreathing Valve</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>K171961</td>
<td>K152521</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. It is intended for over the counter use.</td>
<td>The Seal Rite Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask (without oxygen port) to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (“CPR”) rescue techniques. It is intended for over the counter use.</td>
</tr>
<tr>
<td>Inspiratory Resistance Specification</td>
<td>≤0.5 kPa at 50 L/min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15mmOD: 0.46-0.49 kPa at 50 L/min</td>
<td>0.113 kPa at 50 L/min</td>
</tr>
<tr>
<td></td>
<td>18.5 mm: 0.46-0.48 kPa at 50 L/min</td>
<td></td>
</tr>
<tr>
<td>Expiratory Resistance Specification</td>
<td>≤0.5 kPa at 50 L/min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15mmOD: 0.26-0.30 kPa at 50 L/min</td>
<td>0.0321 kPa at 50 L/min</td>
</tr>
<tr>
<td></td>
<td>18.5 mm: 0.26-0.30 kPa at 50 L/min</td>
<td></td>
</tr>
<tr>
<td>Device Materials</td>
<td>Valve Housing: Rigid styrene-butadiene copolymer Valve Plate: Silicone Filter: Polypropylene</td>
<td>Valve Housing: Polycarbonate Valve Plate: Silicone Filter: Not Described</td>
</tr>
<tr>
<td>Dimensions of Patient Port</td>
<td>15mmOD 18.5mm</td>
<td></td>
</tr>
<tr>
<td>Dimension of Port that Connects to</td>
<td>22 mm</td>
<td>22 mm</td>
</tr>
<tr>
<td>the Mask</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile/Non-Sterile</td>
<td>Non-Sterile</td>
<td>Non-Sterile</td>
</tr>
<tr>
<td>Use</td>
<td>Single Use</td>
<td>Single Use</td>
</tr>
<tr>
<td>Compatibility</td>
<td>Designed for use with standard resuscitation masks</td>
<td>Designed for use with standard resuscitation masks</td>
</tr>
</tbody>
</table>
The Compower Non-Rebreathing Valve has the same indications for use, technological characteristics, principles of operation, material types, performance compliance and biological safety compliance as compared to the predicate device.

The inspiratory resistance and expiratory resistance values are not the same between the subject and predicate devices. The differences can be explained due to slightly different design features of the non-rebreathing valves such as specific filtration media and the design of the exhalation ports. These differences do not raise new issues of safety and efficacy as inspiratory and expiratory requirements of AS 4259 were met by the subject and predicate devices.

There were no significant differences noted between the Compower Non-Rebreathing Valves and the Seal Rite™ Non-Rebreathing Valve that raise new issues of safety and efficacy of the subject device for its intended use. The Compower Non-Rebreathing Valve is substantially equivalent to the predicate Seal Rite™ Non-Rebreathing Valve.

VII. PERFORMANCE DATA
Non-clinical testing was conducted to confirm the conformance of the subject devices to specified requirements. Standards referenced for designing and testing were ISO 5356-1 and AS-4259-1995. Applicable testing was performed on each device model including:

- Visual Inspection
- Dimensional Measurement
- Transparency
- Expiratory resistance of Non-Rebreathing Valve
- Inspiratory resistance of Non-Rebreathing Valve
- Dead Space
- Tensile Testing
- Function after Contamination with Stomach Contents
- Function after Immersion in Water
- Performance After Storage and Aging
- Mean Delivered Oxygen Concentration (Performed for CPR Mask with Oxygen Port Only)

All testing performed passed acceptance criteria demonstrating compliance to relevant standards and supporting the use of the devices for their intended uses.
VIII. BIOCOMPATIBILITY
Biological safety testing was conducted according to Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 16, 2016. All testing passed acceptance criteria when tested according to ISO 10993 requirements.

<table>
<thead>
<tr>
<th>Test</th>
<th>Standard</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity</td>
<td>ISO 10993-5</td>
<td>Pass</td>
</tr>
<tr>
<td>Irritation</td>
<td>ISO 10993-10</td>
<td>Pass</td>
</tr>
<tr>
<td>Sensitization</td>
<td>ISO 10993-10</td>
<td>Pass</td>
</tr>
</tbody>
</table>

IX. CONCLUSION
The Xiamen Compower Medical Tech Co Ltd. CPR Masks with Non-Rebreathing Valves are substantially equivalent to the predicate devices in respect to intended use, technological characteristics and performance.