December 14, 2016

Westmed, Inc.
c/o Paul Dryden
Consultant
5580 S Nogales Hwy
Tucson, Arizona 85706

Re: K162343
Trade/Device Name: Westmed Gas Sampling Cannula with O₂ delivery
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, CAT
Dated: November 10, 2016
Received: November 14, 2016

Dear Paul Dryden:

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 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 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,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

510(k) Number *(if known)*

K162343

Device Name

Westmed Gas Sampling Cannula with O₂ delivery

Indications for Use *(Describe)*

The Westmed nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases. Cumulative duration of use < 24 hours.

Environment of use:
Hospital, sub-acute, and pre-hospital settings

Patient population:
Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics (> 10 kg.).

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*
Proprietary or Trade Name: Westmed Gas Sampling Cannula with O2 delivery

Common/Usual Name: analyzer, gas, carbon-dioxide, gaseous phase (accessories)

Classification Name: analyzer, gas, carbon-dioxide, gaseous phase (accessories)
CCK – CFR 868.1400
Class II

Additional Product Code: cannula, nasal, oxygen
CAT

Predicate Device: K010024 – Oridion
Reference Device: K011050 – Oridion

Device Description: Westmed has designed several O2/CO2 nasal cannula / exhaled gas sampling devices. They include:

- Nasal cannula style that can provide supplemental O2 and sample exhaled gases at only the nares and
- Nasal cannula style that can provide supplemental O2 and sample exhaled gases at both the nares and at the mouth

The device configurations include nasal cannula that have a division to deliver oxygen through one nare and to sample exhaled gases through the other. There is also an oral sampling style which is positioned near the mouth to sample exhaled gases if the patient is a mouth breather.

The device includes a length of standard oxygen tubing and gas sampling lines.

Indications for Use:
The Westmed nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases. Cumulative duration of use < 24 hours.

Environment of use:
Hospital, sub-acute, and pre-hospital settings

Patient population:
Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics (> 10 kg.).

Substantial Equivalence Discussion:

Tables 1 and 2 below compare the key features of the proposed devices with the identified predicates and demonstrate that the proposed device can be found to be substantially equivalent.
### Table 1 – Comparison - O$_2$ delivery / CO$_2$ sampling Cannula style

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Predicate Oridion K010024</th>
<th>Proposed Model 0581</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>To sample exhaled gas via a nasal cannula and simultaneously provide supplemental oxygen near the nose and mouth for inhalation</td>
<td>The Westmed nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases. Cumulative duration of use &lt; 24 hours</td>
</tr>
<tr>
<td><strong>Environments of use</strong></td>
<td>Hospitals, sub-acute, pre-hospital settings</td>
<td>Environment of use: Hospital, sub-acute, and pre-hospital settings</td>
</tr>
<tr>
<td><strong>Patient population</strong></td>
<td>Patient requiring supplemental oxygen and / or sampling of expired gases</td>
<td>Patient population: Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics (&gt;10 kg.)</td>
</tr>
<tr>
<td><strong>Duration of use</strong></td>
<td>Single patient use, disposable</td>
<td>Single patient use, disposable</td>
</tr>
<tr>
<td><strong>Basic components</strong></td>
<td>Channeled / split nasal cannula, Oxygen tubing, Gas sampling line</td>
<td>Channeled / split nasal cannula, Oxygen tubing, Gas sampling line</td>
</tr>
<tr>
<td><strong>Sampling tubing specs</strong></td>
<td>Not provided</td>
<td>ID − 0.060” / OD − 0.109” Length −2” Luer fitting – Male / Female Connected to customer supplied gas sampling line</td>
</tr>
<tr>
<td><strong>Technological characteristics / design</strong></td>
<td>Split nasal cannula with sampling in one nares and oxygen delivery in the other</td>
<td>Split nasal cannula with sampling in one nares and oxygen delivery in the other</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>Flexible PVC for the cannula, oxygen tubing and gas sampling line</td>
<td>Tested to ISO 10993-5 and 10993-10 Flexible PVC for the cannula, oxygen tubing and gas sampling line</td>
</tr>
<tr>
<td><strong>Performance testing</strong></td>
<td></td>
<td>Comparison End-tidal CO$_2$ results and waveform at various settings Tensile strength of connections Luer fitting testing Age testing - Environmental Mechanical testing</td>
</tr>
</tbody>
</table>

### Table 2 – Comparison - O$_2$ delivery / CO$_2$ sampling Oral / Nasal Cannula style

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Reference Oridion K011050</th>
<th>Proposed Model 0430</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>Used whenever the physician needs to measure the CO$_2$ in a patient’s breathing in a non-intubated patient</td>
<td>The Westmed nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases. Cumulative duration of use &lt; 24 hours</td>
</tr>
<tr>
<td><strong>Environments of use</strong></td>
<td>Hospitals, sub-acute, pre-hospital settings</td>
<td>Environment of use: Hospital, sub-acute, and pre-hospital settings</td>
</tr>
<tr>
<td><strong>Patient population</strong></td>
<td>Patient requiring supplemental oxygen and / or sampling of expired gases</td>
<td>Patient population: Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics (&gt;10 kgs.)</td>
</tr>
<tr>
<td><strong>Multiple sizes</strong></td>
<td>Adult to pediatric</td>
<td>Adult to pediatric</td>
</tr>
<tr>
<td><strong>Duration of use</strong></td>
<td>Single patient use, disposable</td>
<td>Single patient use, disposable</td>
</tr>
</tbody>
</table>
### Attribute

<table>
<thead>
<tr>
<th>Basic components</th>
<th>Reference Oridion K011050</th>
<th>Proposed Model 0430</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channeled / split nasal cannula</td>
<td>Mouth sampling option</td>
<td>Oxygen tubing</td>
</tr>
<tr>
<td>Channeled / split nasal cannula</td>
<td>Mouth sampling option</td>
<td>Oxygen tubing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sampling tubing specs</th>
<th>Not provided</th>
<th>ID – 0.060” / OD – 0.109”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length – 7 ft.</td>
<td>Luer fitting – Male / Female</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Technological characteristics / design</th>
<th>Split nasal cannula with sampling in one nares and oxygen delivery in the other and a separate gas sampling placed near the mouth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials</td>
<td>Flexible PVC for the cannula, oxygen tubing and gas sampling line</td>
</tr>
<tr>
<td>Performance testing</td>
<td>Tested to ISO 10993-5 and 10993-10 Flexible PVC for the cannula, oxygen tubing and gas sampling line</td>
</tr>
<tr>
<td>Comparison End-tidal CO₂ results and waveform at various settings</td>
<td></td>
</tr>
<tr>
<td>Tensile strength of connections</td>
<td></td>
</tr>
<tr>
<td>Luer fitting testing</td>
<td></td>
</tr>
<tr>
<td>Age testing - Environmental</td>
<td></td>
</tr>
<tr>
<td>Mechanical testing</td>
<td></td>
</tr>
</tbody>
</table>

Tables 1 and 2 above compare the key features of the proposed Westmed Oxygen delivery / CO₂ sampling cannula style devices with the identified predicate and reference, K010024 and K011050 – Oridion Nasal cannula sampling, and it demonstrates that the proposed devices can be found to be substantially equivalent.

### Discussion of Differences -

#### Indications for Use –
The indications for use are similar for the proposed device when compared to the identified predicate and reference – K010024 and K011050 – Oridion Nasal cannula sampling.

**Discussion** – Each device is indicated for use delivering supplemental oxygen and sampling expired gases.

#### Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the identified predicate and reference – K010024 and K011050 – Oridion Nasal cannula sampling. The materials are similar: flexible PVC for the nasal cannula, oxygen tubing and gas sampling line.

**Discussion** – The design incorporates several styles of split / channeled nasal cannula where oxygen and expired gases are provided through the various ports within the cannula. For the oral / nasal style, there is an extra part which is placed near the mouth to sample expired gases which may be exhaled by the patient.

#### Environment of Use –
The environments of use are similar to identified predicate and reference - K010024 and K011050 – Oridion Nasal cannula sampling.

**Discussion** – The environments of use are not specifically disclosed in the predicate 510(k) Summary, but literature would support the listed environments of use. There are no differences in the requirements of each environment of use which would raise any new safety concerns when compared to the identified predicate and reference – K010024 and K011050 – Oridion Nasal cannula sampling.
Patient Population –
The patient population of pediatrics to adults is equivalent to the identified predicate and reference – K010024 and K011050 – Oridion Nasal cannula sampling.

Discussion – The patient populations are equivalent to the identified predicate and reference - K010024 and K011050 – Oridion Nasal cannula sampling.

Non-Clinical Testing Summary –

Bench Testing -
We performed comparative testing which evaluated the ability to measure a breath, measure a gas, and breathe waveforms under several simulated breathing conditions.

The tests included:
- Comparative CO₂ sampling and waveform performance at 3 different breathing rates, CO₂ concentrations (2% and 5%), and oxygen flow rates (1, 3, and 5 lpm).
- Environmental and Age testing
- Mechanical testing
  - Luer Fitting
  - Flow
  - Strength of bonds
  - Resistance to kinks

The results presented show that the proposed Westmed Oxygen delivery / CO₂ sampling cannula style devices performed equivalent to the predicates.

All testing demonstrated that the proposed devices are substantially equivalent to the identified predicate and reference – K010024 and K011050 – Oridion Nasal cannula sampling.

Biocompatibility –
We have performed ISO 10993 testing on the component materials of the proposed devices which is considered as Externally Communicating and Surface Contact with the patient which means the following tests are required.
- Cytotoxicity
- Sensitization
- Intracutaneous Irritation

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate can be found to be substantially equivalent.