



October 18, 2024

Sleepnet Corporation  
% Paul Dryden  
President  
ProMedic, LLC  
131 Bay Point Dr. NE  
St. Petersburg, Florida 33704

Re: K241830

Trade/Device Name: Mojo Full Face Vented Mask; Veraseal 2 Full Face Vented Mask; Innova Full Face Vented Mask; Ascend Full Face Vented Mask

Regulation Number: 21 CFR 868.5905

Regulation Name: Noncontinuous Ventilator (IPPB)

Regulatory Class: Class II

Product Code: BZD

Dated: September 19, 2024

Received: September 19, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Binoy J.  
Mathews -S**

Digitally signed by Binoy  
J. Mathews -S  
Date: 2024.10.18 15:47:34  
-04'00'

For

Rachana Visaria  
Assistant Director  
DHT1C: Division of Anesthesia,  
Respiratory, and Sleep Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K241830

Device Name

Mojo Full Face Vented Mask, Veraseal 2 Full Face Vented Mask, Innova Full Face Vented Mask, Ascend Full Face Vented Mask

Indications for Use (Describe)

The Sleepnet Mojo Full Face Vented Mask, Veraseal 2 Full Face Vented Mask, Innova Full Face Vented Mask and Ascend Full Face Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bilevel, operating at or above 3 cm H<sub>2</sub>O. The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.

Mojo is intended for Single patient, multi-use in the home or hospital/institutional environment.

Veraseal 2 is intended for Short Term Single Patient use (maximum of 7 days) in the hospital/institutional environment.

Innova is intended for Single patient, multi-use in the home or hospital/institutional environment.

Ascend is intended for Single patient, multi-use in the home or hospital/institutional environment.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**Sponsor:**

Sleepnet Corporation  
5 Merrill Industrial Drive  
Hampton, NH 03842

Tel - 603-758-6625

**Sponsor Contact:**

Jennifer Kennedy – Director of Regulatory and Quality

**Submission Correspondent:**

Paul Dryden  
ProMedic, LLC

**Proprietary or Trade Name:**

Mojo Full Face Vented Mask  
Veraseal 2 Full Face Vented Mask  
Innova Full Face Vented Mask  
Ascend Full Face Vented Mask

**Common/Usual Name:**

Patient interface for CPAP

**Regulation Number:**

21CFR 868.5905

**Regulation Code:**

Non-continuous ventilator (IPPB)

**Product Code:**

BZD

**Predicate Device:**

K120463 – Mojo Full Face Mask and Veraseal Full Face Mask

**Regulation Number:**

21CFR 868.5905

**Regulation Code:**

Non-continuous ventilator (IPPB)

**Product Code:**

BZD

**Device Description:**

The Sleepnet Mojo Vented Full Face Mask, Veraseal 2 Full Face Vented Mask, Innova Full Face Vented Mask and Ascend Full Face Vented Mask are used with positive pressure devices, such as CPAP and Bi-level.

The modifications to the cleared Mojo Full Face mask (K120463) are:

- Addition of contraindication and updated warning related to presence of magnets
- Change to the headgear material
- Addition of an XL size

The modifications to the cleared Veraseal Full Face mask (K120463) are:

- Modified design, now called the Veraseal 2 Full Face Vented Mask
- Addition of an XL size

Other modifications include:

- Addition of the Innova Full Face Vented Mask version
- Addition of the Ascend Full Face Vented Mask version

**Indications for Use:**

The Sleepnet Mojo Full Face Vented Mask, Veraseal 2 Full Face Vented Mask, Innova Full Face Vented Mask and Ascend Full Face Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bilevel, operating at or above 3 cm H<sub>2</sub>O.

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The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.

Mojo is intended for Single patient, multi-use in the home or hospital/institutional environment.

Veraseal 2 is intended for Short Term Single Patient use (maximum of 7 days) in the hospital/institutional environment.

Innova is intended for Single patient, multi-use in the home or hospital/institutional environment.

Ascend is intended for Single patient, multi-use in the home or hospital/institutional environment.

**Patient Population:** For adults (>30 kg)

**Environment of Use:** Home or hospital / institutional environments

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Table of Comparison to Predicate

| Attributes                 | Subject – Mojo, Veraseal 2, Innova, Ascend Full Face Vented Mask                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Predicate – Mojo, Veraseal Full Face Mask, K120463                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Explanation of Differences                          |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Product Classification CFR | BZD<br>CFR 868.5905                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | BZD<br>CFR 868.5905                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Identical                                           |
| List of Devices            | Mojo Full Face Vented Mask<br>Veraseal 2 Full Face Vented Mask<br>Innova Full Face Vented Mask<br>Ascend Full Face Vented Mask                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Mojo Full Face mask<br>Veraseal Full Face mask                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Identical                                           |
| Indications for Use        | <p>The Sleepnet Mojo Full Face Vented Mask, Veraseal 2 Full Face Vented Mask, Innova Full Face Vented Mask and Ascend Full Face Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bilevel, operating at or above 3 cm H<sub>2</sub>O.</p> <p>The masks are to be used on adult patients (&gt;30kg) for whom positive airway pressure therapy has been prescribed.</p> <p><b>Mojo -</b><br/>Single patient, multi-use in the home or hospital/institutional environment.</p> <p><b>Veraseal 2 -</b><br/>Short Term Single Patient use (maximum of 7 days) in the hospital/institutional environment.</p> <p><b>Innova -</b><br/>Single patient, multi-use in the home or hospital/institutional environment.</p> <p><b>Ascend -</b><br/>Single patient, multi-use in the home or hospital/institutional environment.</p> | <p>The Sleepnet Mojo and Veraseal masks are intended to be used with positive airway pressure devices, such as CPAP or bilevel, operating at or above 3 cm H<sub>2</sub>O. The masks are to be used on adult patients (&gt;30kg) for whom positive airway pressure therapy has been prescribed.</p> <p><b>Mojo –</b><br/>Single patient, multi-use and Multi-patient, multi-use</p> <p><b>Veraseal –</b><br/>Disposable single use; Single patient, multi-use up to 7 days</p> <p>The masks are intended for use in the home or hospital/institutional environment.</p> | Similar.<br>The multi-patient use is being removed. |
| Patient Population         | Adult (>30 kg)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Adult (>30 kg)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Identical                                           |

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| Attributes                           | Subject – Mojo, Veraseal 2, Innova, Ascend Full Face Vented Mask                                                                                                                                                       | Predicate – Mojo, Veraseal Full Face Mask, K120463                                                                                                                                                           | Explanation of Differences                                                                                                                                                       |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Patient type                         | Patients who are appropriate candidates for positive pressure therapy                                                                                                                                                  | Patients who are appropriate candidates for positive pressure therapy                                                                                                                                        | Identical                                                                                                                                                                        |
| Prescriptive                         | Yes                                                                                                                                                                                                                    | Yes                                                                                                                                                                                                          | Identical                                                                                                                                                                        |
| Environment of Use                   | The masks are intended for use in the home or hospital/institutional environment.                                                                                                                                      | The masks are intended for use in the home or hospital/institutional environment.                                                                                                                            | Identical                                                                                                                                                                        |
| Duration of Use                      | <b>Mojo -</b><br>Single patient, multi-use<br><b>Veraseal 2 -</b><br>Short Term Single Patient use (maximum of 7 days)<br><b>Innova -</b><br>Single patient, multi-use<br><b>Ascend -</b><br>Single patient, multi-use | <b>Mojo –</b><br>Single patient, multi-use and Multi-patient, multi-use<br><b>Veraseal –</b><br>Disposable single use; Single patient, multi-use up to 7 days                                                | Similar.<br>Multi-patient use for the Mojo mask is being removed.<br><br>Single use for the Veraseal mask is being removed.                                                      |
| Principle of Operation               | Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a positive pressure device. Mask includes an exhalation port and AAV for flushing out exhaled CO <sub>2</sub> .           | Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a positive pressure device. Mask includes an exhalation port and AAV for flushing out exhaled CO <sub>2</sub> . | Identical                                                                                                                                                                        |
| Therapy Pressure                     | Greater than 3 cm H <sub>2</sub> O<br>Typically determined by the equipment to which it is attached.                                                                                                                   | Greater than 3 cm H <sub>2</sub> O<br>Typically determined by the equipment to which it is attached.                                                                                                         | Identical                                                                                                                                                                        |
| Anatomical site                      | Face (seals around nose and mouth)                                                                                                                                                                                     | Face (seals around nose and mouth)                                                                                                                                                                           | Identical                                                                                                                                                                        |
| User Interface to administer therapy | Masks have a standard 22mm connector (compliant with ISO 5356-1) that connects to 22mm CPAP circuits.                                                                                                                  | Mask has a standard 22mm connector (compliant with ISO 5356-1) that connects to 22mm CPAP circuits.                                                                                                          | Identical                                                                                                                                                                        |
| Contraindications                    | Mojo has an contraindication that is identical to the predicate K120463. Veraseal 2, Innova and Ascend do not have contraindications.                                                                                  | Mojo mask has a contraindication.                                                                                                                                                                            | Similar. The first contraindication in the Mojo mask is identical to the predicate.<br><br>New contraindication related to presence of magnets added as per recall event #94169. |

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| Attributes | Subject – Mojo, Veraseal 2, Innova, Ascend Full Face Vented Mask                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Predicate – Mojo, Veraseal Full Face Mask, K120463 | Explanation of Differences              |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------------------|
|            | <p><u>New Contraindication (Mojo only)</u></p> <p>Do not use this mask if you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets. Implant examples include, but are not limited to, pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, aneurysm clips, metallic stents, ocular implants, insulin/infusion pumps, cerebral spinal fluid (CSF) shunts, embolic coils, metallic splinter, implants to restore hearing or balance with implanted magnets (such as cochlear implants), flow disruption devices, contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, bone substitute device, magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher, etc. If you have any questions regarding the implant, consult your physician or the manufacturer of your implant.</p> |                                                    |                                         |
| Warnings   | <p><u>Updated Warning</u></p> <p>Magnets are used in the mask and headgear clips with a field strength of 380mT. With the exception of the devices identified in the contraindication, ensure that the mask is kept at least 6 inches (approx. 16 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. For instance, the functioning of implants may change, or implants may move within the body due to magnetic attraction/repulsion. This applies to you or anyone in close physical contact with your mask.</p>                                                                                                                                                                                                                                                                                                                                                                                       | Unchanged from K120463                             | Updated warning for magnets to labeling |

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| Attributes                   | Subject – Mojo, Veraseal 2, Innova, Ascend Full Face Vented Mask                                                                                                                                                                   | Predicate – Mojo, Veraseal Full Face Mask, K120463                                                                                                                       | Explanation of Differences                                                                                                                                                                                                 |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Useful life                  | <b>Mojo -</b><br>Single patient use - 6 months<br><b>Veraseal 2 -</b><br>Short Term Single Patient use (maximum of 7 days)<br><b>Innova -</b><br>Single patient use - 6 months<br><b>Ascend -</b><br>Single patient use - 6 months | <b>Mojo –</b><br>Single patient, multi-use and Multi-patient, multi-use – 6 months<br><b>Veraseal –</b><br>Disposable single use; Single patient, multi-use up to 7 days | Similar.<br>Multi-patient use for Mojo mask has been removed.<br>Single use for Veraseal mask has been removed.                                                                                                            |
| Non-sterile                  | Yes                                                                                                                                                                                                                                | Yes                                                                                                                                                                      | Identical                                                                                                                                                                                                                  |
| Cleaning methods             | <b>Mojo -</b><br>Mild Soap and water<br><b>Veraseal 2 -</b><br>Mild Soap and water<br>Isopropyl alcohol<br><b>Innova -</b><br>Mild Soap and water<br><b>Ascend -</b><br>Mild Soap and water                                        | <b>Mojo -</b><br>Mild Soap and water<br><b>Veraseal -</b><br>Mild Soap and water<br>Isopropyl alcohol                                                                    | Identical                                                                                                                                                                                                                  |
| <b>Features</b>              |                                                                                                                                                                                                                                    |                                                                                                                                                                          |                                                                                                                                                                                                                            |
| Available sizes              | <b>Mojo – 4</b><br><b>Veraseal 2 – 4</b><br><b>Innova – 3</b><br><b>Ascend - 3</b>                                                                                                                                                 | <b>Mojo – 3</b><br><b>Veraseal - 3</b>                                                                                                                                   | Similar.<br>XL size has been added to the Mojo and Veraseal 2 masks. These sizes utilize all the same components as the corresponding large size, except for the gel cushion which is slightly larger in length and width. |
| Shape                        | Similar                                                                                                                                                                                                                            | Similar                                                                                                                                                                  | Similar                                                                                                                                                                                                                    |
| Incorporates an Exhaust port | Yes                                                                                                                                                                                                                                | Yes                                                                                                                                                                      | Identical                                                                                                                                                                                                                  |

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| Attributes                         | Subject – Mojo, Veraseal 2, Innova, Ascend Full Face Vented Mask                                                                                                                                                                                                                                               | Predicate – Mojo, Veraseal Full Face Mask, K120463                                                                                                                              | Explanation of Differences                                                                                                                                                                                                                           |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Components of the mask             | <ul style="list-style-type: none"> <li>Mask shell</li> <li>Gel bladder (cushion)</li> <li>Vented elbow assembly</li> <li>Forehead arm/forehead pad</li> <li>Headgear</li> </ul>                                                                                                                                | <ul style="list-style-type: none"> <li>Mask shell</li> <li>Gel bladder (cushion)</li> <li>Vented elbow assembly</li> <li>Forehead arm/forehead pad</li> <li>Headgear</li> </ul> | Similar                                                                                                                                                                                                                                              |
| Shell design                       | <b>Mojo</b> – soft shell<br><b>Veraseal 2</b> – hard shell<br><b>Innova</b> – hard shell<br><b>Ascend</b> – hard shell                                                                                                                                                                                         | <b>Mojo</b> – soft shell<br><b>Veraseal 2</b> – hard shell                                                                                                                      | Identical                                                                                                                                                                                                                                            |
| Patient Contact per ISO 10993-1    | Skin contact<br>Externally Communicating with tissue (air pathway)<br>Permanent contact                                                                                                                                                                                                                        | Skin contact<br>Externally Communicating with tissue (air pathway)<br>Permanent contact                                                                                         | Identical                                                                                                                                                                                                                                            |
| <b>Performance Characteristics</b> |                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                 |                                                                                                                                                                                                                                                      |
| Deadspace                          | <b>Mojo</b><br>Small 160 ml<br>Medium 185 ml<br>Large 205 ml<br>XL 210 ml<br><b>Veraseal 2</b><br>Small 155.3 ml<br>Medium 181.7 ml<br>Large 196.6 ml<br>XL 200.6 ml<br><b>Innova</b><br>Small 155.3 ml<br>Medium 181.7 ml<br>Large 196.6 ml<br><b>Ascend</b><br>Small 165 ml<br>Medium 212 ml<br>Large 221 ml | <b>Mojo</b><br>Small 160 ml<br>Medium 185 ml<br>Large 205 ml<br><b>Veraseal</b><br>Small 138 ml<br>Medium 165 ml<br>Large 181 ml                                                | Similar.<br>XL size has been added to the Mojo and Veraseal 2 masks. The deadspace for all subject devices is within 5% of the predicate Mojo mask. The CO <sub>2</sub> washout profile of all the subject devices has been verified to be adequate. |

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| Attributes                    | Subject – Mojo, Veraseal 2, Innova, Ascend Full Face Vented Mask                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | Predicate – Mojo, Veraseal Full Face Mask, K120463                                                                                                                                                        |            | Explanation of Differences                                                                                         |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------|-------|----|-------|----|-------|-------------------------------|------------|---|-------|----|-------|----|-------|-------------------------------|------------|---|-------|----|-------|----|-------|-------------------------------|------------|---|-------|----|-------|----|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-------------------------------|------------|---|-------|----|-------|----|-------|-------------------------------|------------|---|-------|----|-------|----|-------|---------------------------------------------------------------------------------------------------|
| Exhaust flow characteristics  | <p><b>Mojo</b></p> <table><tr><td>Pressure (cmH<sub>2</sub>O)</td><td>Flow (lpm)</td></tr><tr><td>3</td><td>17.88</td></tr><tr><td>10</td><td>32.57</td></tr><tr><td>20</td><td>48.90</td></tr></table> <p><b>Veraseal 2</b></p> <table><tr><td>Pressure (cmH<sub>2</sub>O)</td><td>Flow (lpm)</td></tr><tr><td>3</td><td>22.08</td></tr><tr><td>10</td><td>38.50</td></tr><tr><td>20</td><td>54.30</td></tr></table> <p><b>Innova</b></p> <table><tr><td>Pressure (cmH<sub>2</sub>O)</td><td>Flow (lpm)</td></tr><tr><td>3</td><td>22.08</td></tr><tr><td>10</td><td>38.50</td></tr><tr><td>20</td><td>54.30</td></tr></table> <p><b>Ascend</b></p> <table><tr><td>Pressure (cmH<sub>2</sub>O)</td><td>Flow (lpm)</td></tr><tr><td>3</td><td>26.80</td></tr><tr><td>10</td><td>41.50</td></tr><tr><td>20</td><td>58.00</td></tr></table> |  | Pressure (cmH <sub>2</sub> O)                                                                                                                                                                             | Flow (lpm) | 3                                                                                                                  | 17.88 | 10 | 32.57 | 20 | 48.90 | Pressure (cmH <sub>2</sub> O) | Flow (lpm) | 3 | 22.08 | 10 | 38.50 | 20 | 54.30 | Pressure (cmH <sub>2</sub> O) | Flow (lpm) | 3 | 22.08 | 10 | 38.50 | 20 | 54.30 | Pressure (cmH <sub>2</sub> O) | Flow (lpm) | 3 | 26.80 | 10 | 41.50 | 20 | 58.00 | <p><b>Mojo</b></p> <table><tr><td>Pressure (cmH<sub>2</sub>O)</td><td>Flow (lpm)</td></tr><tr><td>3</td><td>21.20</td></tr><tr><td>10</td><td>37.20</td></tr><tr><td>20</td><td>53.10</td></tr></table> <p><b>Veraseal</b></p> <table><tr><td>Pressure (cmH<sub>2</sub>O)</td><td>Flow (lpm)</td></tr><tr><td>3</td><td>21.10</td></tr><tr><td>10</td><td>36.40</td></tr><tr><td>20</td><td>53.00</td></tr></table> |  | Pressure (cmH <sub>2</sub> O) | Flow (lpm) | 3 | 21.20 | 10 | 37.20 | 20 | 53.10 | Pressure (cmH <sub>2</sub> O) | Flow (lpm) | 3 | 21.10 | 10 | 36.40 | 20 | 53.00 | Similar.<br>The exhaust flow characteristics of the subject devices are similar to the predicate. |
| Pressure (cmH <sub>2</sub> O) | Flow (lpm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 3                             | 17.88                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 10                            | 32.57                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 20                            | 48.90                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| Pressure (cmH <sub>2</sub> O) | Flow (lpm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 3                             | 22.08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 10                            | 38.50                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 20                            | 54.30                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| Pressure (cmH <sub>2</sub> O) | Flow (lpm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 3                             | 22.08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 10                            | 38.50                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 20                            | 54.30                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| Pressure (cmH <sub>2</sub> O) | Flow (lpm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 3                             | 26.80                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 10                            | 41.50                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 20                            | 58.00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| Pressure (cmH <sub>2</sub> O) | Flow (lpm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 3                             | 21.20                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 10                            | 37.20                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 20                            | 53.10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| Pressure (cmH <sub>2</sub> O) | Flow (lpm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 3                             | 21.10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 10                            | 36.40                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| 20                            | 53.00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                                                                           |            |                                                                                                                    |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |
| AAV Opening/Closing Pressure  | <p><b>Mojo</b></p> <p>Opening - 1.10 cm H<sub>2</sub>O</p> <p>Closing – 1.60 cm H<sub>2</sub>O</p> <p><b>Veraseal</b></p> <p>Opening – 2.1 cm H<sub>2</sub>O</p> <p>Closing – 2.28 cm H<sub>2</sub>O</p> <p><b>Innova</b></p> <p>Opening - 2.1 cm H<sub>2</sub>O</p> <p>Closing – 2.28 cm H<sub>2</sub>O</p> <p><b>Ascend</b></p> <p>Opening – 1.92 cm H<sub>2</sub>O</p> <p>Closing – 1.85 cm H<sub>2</sub>O</p>                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <p><b>Mojo</b></p> <p>Opening - 1.10 cm H<sub>2</sub>O</p> <p>Closing – 1.60 cm H<sub>2</sub>O</p> <p><b>Veraseal</b></p> <p>Opening – 1.29 cm H<sub>2</sub>O</p> <p>Closing – 1.45 cm H<sub>2</sub>O</p> |            | Similar.<br>Pass/Fail criteria as per ISO 17510 is < 3 cm H <sub>2</sub> O. All subject devices meet the criteria. |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                               |            |   |       |    |       |    |       |                               |            |   |       |    |       |    |       |                                                                                                   |

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|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Resistance to Flow<br>(Pressure drop) | <b>Mojo</b><br>50 lpm – 0.40 cm H <sub>2</sub> O<br>100 lpm – 0.65 cm H <sub>2</sub> O<br><b>Veraseal 2</b><br>50 lpm – 0.07 cm H <sub>2</sub> O<br>100 lpm – 0.39 cm H <sub>2</sub> O<br><b>Innova</b><br>50 lpm – 0.07 cm H <sub>2</sub> O<br>100 lpm – 0.39 cm H <sub>2</sub> O<br><b>Ascend</b><br>50 lpm – 0.11 cm H <sub>2</sub> O<br>100 lpm – 0.59 cm H <sub>2</sub> O                                                                                                                                                                                                                                                                                                                                         | <b>Mojo</b><br>50 lpm – 0.40 cm H <sub>2</sub> O<br>100 lpm – 0.65 cm H <sub>2</sub> O<br><b>Veraseal</b><br>50 lpm – 0.49 cm H <sub>2</sub> O<br>100 lpm – 0.89 cm H <sub>2</sub> O                                                                                                                                                                          | Similar.<br>There are no acceptance criteria in ISO 17510 for resistance to flow (pressure drop). The resistance values are disclosed in the IFU's. |
| Magnets                               | <b>Mojo only</b><br>4 Magnets are used in the mask (2) and headgear clips (2) with a field strength of 380mT. These are identical to K190254.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No magnets                                                                                                                                                                                                                                                                                                                                                    | Reference K190254                                                                                                                                   |
| CO2 washout profile<br>ISO 17510:2015 | <b>Mojo -</b><br>Setting      etCO <sub>2</sub> (%increase vs baseline)<br>3 cmH <sub>2</sub> O                      5.1 (0 %)<br>5 cmH <sub>2</sub> O                      3.5 (-31 %)<br>10 cmH <sub>2</sub> O                      2.1 (-58 %)<br>SingleFault1                      7.4 (48 %)<br>SingleFault2                      7.5 (51 %)<br><br><b>Veraseal 2 / Innova</b><br>Setting      etCO <sub>2</sub> (%increase vs baseline)<br>3 cmH <sub>2</sub> O                      5.9 (16 %)<br>5 cmH <sub>2</sub> O                      5.9 (16 %)<br>10 cmH <sub>2</sub> O                      5.7 (12 %)<br>SingleFault1                      6.4 (25 %)<br>SingleFault2                      7.4 (45 %) | <b>Mojo and Veraseal -</b><br>Setting      etCO <sub>2</sub> (%increase vs baseline)<br>3 cmH <sub>2</sub> O                      6.1 (17 %)<br>5 cmH <sub>2</sub> O                      5.9 (14 %)<br>10 cmH <sub>2</sub> O                      5.8 (12 %)<br>SingleFault1                      6.3 (21 %)<br>SingleFault2                      Not tested | Similar, complies with ISO 17510                                                                                                                    |

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|                                                                          |                                                                                                                                                                                                                                     |                                                                                                                                                                                                                 |              |
|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                                                                          | <b>Ascend</b><br>Setting etCO <sub>2</sub> (%increase vs baseline)<br>3 cmH <sub>2</sub> O 5.0 (0 %)<br>5 cmH <sub>2</sub> O 5.0 (0 %)<br>10 cmH <sub>2</sub> O 4.8 (-4 %)<br>SingleFault1 6.5 (30 %)<br>SingleFault2 7.3 (46 %)    |                                                                                                                                                                                                                 |              |
| Sound Pressure and<br>Sound Power Level                                  | <b>Mojo</b><br>Sound Pressure – 30.07 dBA<br>Sound Power – 33.09 dBA<br><br><b>Veraseal 2 / Innova / Ascend</b><br>Sound Pressure – 29.98 dBA<br>Sound Power – 32.99 dBA                                                            | <b>Mojo</b><br>Sound Pressure – 30.07 dBA<br>Sound Power – 33.09 dBA<br><br><b>Veraseal</b><br>Sound Pressure – 29.98 dBA<br>Sound Power – 32.99 dBA                                                            | From K120463 |
| AAV<br>Inspiratory/Expiratory<br>Resistance in Single Fault<br>Condition | <b><u>Mojo®</u></b><br>Inspiratory - 0.8 cm H <sub>2</sub> O<br>Expiratory – 0.8 cm H <sub>2</sub> O<br><b><u>Veraseal 2 / Innova / Ascend</u></b><br>Inspiratory – 0.6 cm H <sub>2</sub> O<br>Expiratory – 0.5 cm H <sub>2</sub> O | <b><u>Mojo®</u></b><br>Inspiratory - 0.8 cm H <sub>2</sub> O<br>Expiratory – 0.8 cm H <sub>2</sub> O<br><b><u>Veraseal</u></b><br>Inspiratory – 0.8 cm H <sub>2</sub> O<br>Expiratory – 0.8 cm H <sub>2</sub> O | From K120463 |

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**Substantial Equivalence Discussion:**

The Sleepnet Mojo Full Face Vented Mask, Veraseal 2 Full Face Vented Mask, Innova Full Face Vented Mask and Ascend Full Face Vented Mask are viewed as substantially equivalent to the predicate device because:

**Indications –**

- The Indications for are similar to the predicate.
- Similar to the predicate – K120463.

**Patient Population –**

- The masks are to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed.
- Identical to the predicate – K120463.

**Environment of Use –**

- The masks are intended for use in the home or hospital/institutional environment.
- Identical to the predicate – K120463.

**Technological Characteristics –**

- Identical technology to the predicate – K120463.

**Non-Clinical Testing Summary –**

**Bench testing** – Testing demonstrating conformance to ISO 17510 - Medical Devices – Sleep Apnoea Breathing Therapy - Masks And Application Accessories:

- Exhaust flow
- Resistance to Flow
- Anti-asphyxia valve (AAV) pressure test
- AAV Inspiratory/Expiratory Resistance in Single Fault Condition
- Internal Volume / Dead space
- CO<sub>2</sub> rebreathing

*Discussion* – The performance test results from the predicate device were leveraged for the Mojo and Veraseal 2 models. New testing was conducted for the Innova and Ascend models.

**Biocompatibility –**

The materials in gas pathway and skin contact for all subject devices are identical to Sleepnet's own devices cleared under K120463 and K190254, which have similar intended use, environment of use, and duration of use as the subject devices using material certifications.

*Discussion* – The biocompatibility test results from the predicate device were leveraged for all subject devices.

**Transportation and Shelf-life –**

There have been no changes in the transportation or shelf-life – the subject devices leverage the predicate device testing for transportation and shelf-life.

*Discussion* – The performance post transportation and shelf-life test results from the predicate device were leveraged for the subject device.

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**Reprocessing –**

There has been no change in the reprocessing – the subject and predicate device utilize the same reprocessing instructions.

*Discussion* – The reprocessing test results from the predicate device were leveraged for the subject device.

**Substantial Equivalence Conclusion**

We have demonstrated that the subject devices are equivalent to the predicate, K120463.