DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2015

Sommetrics
c/o Paul Dryden
Promedic Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958

Re: DEN140024
cNEP Airway Management System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 868.5105
Regulation Name: External Negative Pressure Airway Aid
Regulatory Classification: Class II
Product Code: PMB
Dated: August 18, 2014
Received: August 15, 2014

Dear Mr. Dryden:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the cNEP Airway Management System, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> *The cNEP Airway Management System is to be used as an aid for maintaining the patency of the upper airway in spontaneously breathing adults undergoing medical procedures less than 2 hours in duration, where the patient is intended to have mild to moderate sedation with non-propofol containing medications.*

FDA concludes that this device should be classified into class II. This order, therefore, classifies the cNEP Airway Management System, and substantially equivalent devices of this generic type, into class II under the generic name, External Negative Pressure Airway Aid.

FDA identifies this generic type of device as:

> **External Negative Pressure Airway Aid**. An external negative pressure airway aid is a prescription device that applies negative pressure to a patient's neck to aid in providing a patent airway during procedures requiring anesthesia.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not

substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On August 18, 2014, FDA received your *de novo* requesting classification of the cNEP Airway Management System into class I. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the cNEP Airway Management System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the cNEP Airway Management System indicated for the following:

> *The cNEP Airway Management System is to be used as an aid for maintaining the patency of the upper airway in spontaneously breathing adults undergoing medical procedures less than 2 hours in duration, where the patient is intended to have mild to moderate sedation with non-propofol containing medications*

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Impaired blood flow	• Clinical Performance Testing
Failure of device or negative pressure mechanism	• Non-clinical Performance Testing
Adverse tissue reaction	• Biocompatibility
Dislodging of plaque, leading to possible stroke	• Labeling
Inadequate collar fit	• Labeling
Use error	• Labeling

In combination with the general controls of the FD&C Act, the External Negative Pressure Airway Aid is subject to the following special controls:

1. Clinical performance testing must document any adverse events observed during clinical use, including impaired blood flow, and demonstrate that the device performs as intended under anticipated conditions.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated patient positions, does not fail during use and does not lose negative pressure capability. The following testing should be performed:

    a. Ability of the device to maintain a seal during various patient positions
    b. Device leakage testing to demonstrate the device maintains vacuum
    c. Drop testing to ensure the device does not incur functional damage after dropping the device
    d. Functional testing after high and low storage temperature.

3. All patient contacting components must be demonstrated to be biocompatible.

4. Labeling must include:

    a. A summary of clinical testing results, including any adverse events and evidence that effectiveness has been achieved.

    b. Technical specifications of the device, including collar sizes, maximum duration of use, operating temperature and storage temperature range.

    c. Technical specifications of the vacuum source, including maximum vacuum level and operational vacuum level.

    d. Instructions for use that includes how to place the device, determination of size, verification of suction, reference to training materials and information on troubleshooting the device if it does not attach properly.

    e. A warning to screen patients for carotid artery disease due to the probable risk of the device to dislodge arterial plaques in the carotid artery.

    f. A warning to exclude patients with anatomical abnormalities.

    g. A warning not to use the device during medical procedures involving medications that contain propofol.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this

device type must submit a premarket notification containing information on the External Negative Pressure Airway Aid they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Neha Gujarati at 301-796-9568.

Sincerely yours,

Sergio M. De Del Castillo -S

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