February 16, 2018

NeVap, Inc.
% Janet Kwiatkowski
President
MAE Consulting Group, LLC
119 North Road
Deerfield, New Hampshire 03037

Re: K172208
Trade/Device Name: NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with Preloaded Stylet
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: January 17, 2018
Received: January 18, 2018

Dear Janet Kwiatkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172208

Device Name
NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with Preloaded Stylet

Indications for Use *(Describe)*
NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with Preloaded Stylet is indicated for oral/tracheal intubation for anesthesia, airway management and removal of accumulated subglottic secretions. It is indicated for single-patient, single-use only.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Section 5- 510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary for the use of the NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with preloaded stylet.

5.1. Applicant:

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5.2. Sponsor Contact Person:

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5.3. Regulatory Correspondent/ 510(k) Submission Contact:

Janet Kwiatkowski
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5.4. Date Prepared: February 16, 2018

5.5. Device Information:

Proprietary Name: NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with Preloaded Stylet

	Endotracheal Tube
Panel:	Anesthesiology
Regulatory Number:	21 CFR 868.5730
Regulation Name:	Tube, Tracheal (W/Wo Connector)

Product Code: BTR
Device Class: Class II

5.6. Predicate Device:

- TaperGuard Evac™ Endotracheal Tubes (K090352)

5.7. Device Description:

The NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with preloaded stylet is a disposable, sterile, single-patient, single use device. The NeVap ASSET is packaged individually and supplied sterile with a standard 15mm connector and preloaded stylet. The NeVap ASSET is a Magill curved construction with primary lumen for patient ventilation. Two (2) narrower lumens within the primary wall are used for cuff inflation and subglottic evacuation (vacuum). A low pressure, conformable cuff is inflated through the inflation line with pilot balloon using a standard 10cc syringe (air only) through a one-way check valve. For evacuation of subglottic secretions, a separate (yellow) suction line, with male fitting, connects to standard hospital vacuum receptacles. Once properly intubated, subglottic secretions are evacuated through the suction appendage just superior to the cuff. To facilitate proper positioning, the suction appendage and lumen line marker are radiopaque.

5.8. Indication for Use:

The NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with preloaded stylet is indicated for oral/tracheal intubation for anesthesia, airway management and removal of accumulated subglottic secretions. It is indicated for single-patient, single-use only.

5.9. Comparison of Technological Characteristics:

The NeVap Aspire Subglottic Suction Endotracheal Tube is substantially equivalent in intended use, design, performance and principles of operation to the predicate device. Both are polyvinylchloride tubes with a polyvinylchloride inflatable cuff and a suction lumen. Both incorporate a suction valve with integrated rinse port to aid in removing secretions that accumulate in the subglottic space. Both are provided with an additional preloaded stylet. The differences between the NeVap Aspire Subglottic Suction Endotracheal tube and the predicate device raise no different issues of safety and effectiveness. The NeVap Aspire Subglottic Suction Endotracheal Tube with Preloaded Stylet and the predicate device consist of the same fundamental technology and are sterilized with acceptable methods. Below is a comparison table that summarizes the technological characteristics of the subject and predicate endotracheal tubes.

Comparative Characteristics	**Proposed Device: NeVap Aspire Subglottic Suction Endotracheal Tube with Preloaded Stylet**	**Predicate Device: TaperGuard Evac™ Endotracheal Tubes**
510(k) Number	N/A	K090352
Indication for Use	The NeVap ASSET is indicated for oral/tracheal intubation for anesthesia, airway management and removal of accumulated subglottic secretions. It is indicated for single-patient, single-use only.	The TaperGuard Evac™ Endotracheal tube is indicated for airway management by oral/nasal intubation of the trachea, and for evacuation or drainage of the subglottic space.
Anatomical site	The NeVap ASSET is placed inside the patient's tracheal airway via oral intubation.	The TaperGuard Evac Endotracheal tube is a device inserted into a patient's trachea via the nose or mouth to maintain an open airway.
Materials		
Endotracheal Tube/ Main Tube	Polyvinyl Chloride Compound with Radiopaque marker	Same
Pilot Balloon	PVC Pilot Balloon	Same
Inflation tube/tail	PVC	Same
Cuff Balloon	PVC with a cylindrical shape	PVC with a tapered shape
Male Suction Lumen Connector	PVC	Same
Design		
Preloaded Stylet	Yes	Yes
Descriptive Size (ID)	6.0, 6.5, 7.0, 7.5, 8.0, 8.5 (mm)	TaperGuard Evac™ Endotracheal Tube - Oral (6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm)
Magill Curve	Yes	Same
Murphy eye	Yes	Same
15mm Connector	Yes	Same
Radiopaque Line	Yes	Same
Suction port for removal of secretions that accumulate above the cuff balloon	Radial Multiport Suction T o The multiport Suction-T component is located above the cuff and extends in a semi-circular manner around the external surface of the endotracheal tube to facilitate evacuation of secretions accumulating above the cuff.	Single Suction Port o The single suction port is located above the cuff with an evacuation lumen to facilitate evacuation of secretions accumulating above the cuff.

Comparative Characteristics	**Proposed Device: NeVap Aspire Subglottic Suction Endotracheal Tube with Preloaded Stylet**	**Predicate Device: TaperGuard Evac™ Endotracheal Tubes**
Do the devices have the same technological characteristics?	• As compared above, the intended use is the same. This device specifies the device for single use. o The indications for use statements are nearly identical for the two devices except that the predicate device can be inserted in the patient's trachea through oral and nasal intubation, whereas the proposed device can be inserted only through oral intubation. The proposed device specifies the device for single use, in compliance to the recognized labeling standards. o Although worded differently, the indications for use identify the similar Intended use i.e., both devices are used for airway management and removal of accumulated subglottic secretions above the endotracheal cuff. o The proposed device meets the performance functional tests specification and biocompatibility test requirements. Additionally, the potential hazards and use-related issues associated with the proposed device have been adequately mitigated in the risk analysis and device user interface has been adequately demonstrated in Human Factors/Usability study. Please see summary of testing for the proposed device in the section 5.10 below. All the test reports have been provided in this 510(k). o The test results support the conclusion that the differences in the indication for use statement is not critical and does not affect the safety and effectiveness of the device when used as labeled in accordance with 21 CFR 807.92(a)(5). • There exist a minor difference between the design and materials o A risk analysis has been established for the Suction-T component in accordance with ISO 14971. The potential hazards including tissue damage, dislodgement, and device material failure have been identified and mitigated to acceptable risk levels. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment. Please see summary of testing for Suction-T in the section below. • Biocompatibility and performance testing were conducted, and the results demonstrate substantial equivalence.	

5.10. Summary of Testing

To ensure that the device design and construction are suitable for the intended use, the NeVap ASSET with Preloaded Stylet has been evaluated in the following tests:

- Performance Bench testing has been conducted to verify that the performance of the proposed NeVap ASSET with Preloaded Stylet is substantially equivalent to the predicate device, and that the NeVap ASSET with preloaded stylet will perform as intended. Bench-top testing was conducted to assure conformance to the following standards:
    - ISO 5361:2016- Anaesthetic And Respiratory Equipment - Tracheal Tubes and Connectors
    - ISO 5356-1:2015- Anaesthetic and Respiratory Equipment -- Conical connectors -- Part 1: Cones and sockets
- The following Biocompatibility testing was performed in accordance with ISO 10993-1:2009 and FDA guidance on Use of International Standard ISO 10993-1
    - Cytotoxicity
    - Implantation
    - Sensitization
    - Irritation / Intracutaneous reactivity
    - Material Mediated Pyrogenicity
    - Chemical Characterization- Extractable and Leachable
    - Toxicological Risk Assessment
- Sterilization by ethylene oxide has been validated for NeVap ASSET with preloaded stylet.
- A Human Factors / Usability Study was conducted and the NeVap ASSET with preloaded stylet was found to be in conformance with the IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- Clinical Testing was not conducted. Clinical evidence was not necessary to show substantial equivalence
- A risk analysis according to ISO standard “14971 Medical Devices – Application of risk management to medical devices” was carried out for the NeVap ASSET with preloaded stylet. Possible hazards and consequences were systematically identified and evaluated by using the “Failure Mode and Effect Analysis” technique.
- The following bench testing was conducted to support the performance of the Suction-T component of NeVap ASSET with preloaded stylet. The test results demonstrated that the device meets the performance requirements for its intended use:
    - Suction Patency Test
    - Fluid Recovery Rates determination
    - Suction-T Pull Test (Shear and Tensile Force)
    - Isolated Suction-T Material Pull Test

5.11. Conclusion:

The NeVap ASSET with Preloaded Stylet met all predetermined acceptance criteria as specified by the applicable standards, FDA guidance documents and test protocols. Therefore, the NeVap ASSET with preloaded stylet is considered substantially equivalent to the predicate device.