DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 20, 2015

Davis Medical, LLC
% Ms. Michelle Lott
Owner (President)
Lean RAQA Systems
12602 N. Summer Wind Drive
Marana, AZ 85658

Re: K141747
Trade/Device Name: Rhinoguard
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: March 19, 2015
Received: March 20, 2015

Dear Ms. Lott,

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141747

Device Name
Rhinoguard

Indications for Use *(Describe)*
The Rhinoguard is a nasal endotracheal tube introducer/dilator designed to allow the passage of a nasal endotracheal tube from the nares to the oropharynx.
The device can be used with cuffed and non-cuffed nasal endotracheal tubes.

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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SECTION 5
510(K) SUMMARY

510(k) Summary

As required by 21 CFR 807.92, this "510(k) Summary" provides a basis for the substantial equivalence determination of the device listed below.

General Information

Date Prepared: June 27th, 2014

510(k) Submitter:
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510(k) Correspondent:
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Attn: Michelle Lott
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Contact: Michelle Lott, RAC
(520) 275-9838
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Device Information

Trade Name: Rhinoguard
Common Name: Endotracheal Tube Introducer
Classification Name: Tubes, Tracheal (W/Wo Connector)
[21 CFR 868.5730, Product Code BTR]
Classification Panel: Anesthesiology
Class: Class II

Predicate Device Information

Trade Name: Rusch Preformed AGT Nasal Endotracheal Tubes (cuffed & uncuffed)
Common Name: Endotracheal Tube Introducer
Classification Name: Tubes, Tracheal (W/Wo Connector)
[21 CFR 868.5730, Product Code BTR]
Classification Panel: Anesthesiology
Class: Class II
510(k) Number: K931164 & K931165

Device Description

The Rhinoguard is a nasal endotracheal tube introducer/dilator designed to ease the passage of a nasal endotracheal tube from the nares to the oropharynx. The Rhinoguard device is constructed primarily of polyvinylchloride and consists of a tube with a hollow proximal end, a tapered cylindrical body and a closed, rounded distal end. The device has markings to indicate the approximate mating location for corresponding sizes of nasal endotracheal tubes. The device is provided in a small and large size. The small Rhinoguard is intended to mate with 3.0 to 4.5 mm nasal endotracheal tubes and the large

Rhinoguard is intended to mate with 5.0 to 8.0 mm nasal endotracheal tubes. The device can be used with cuffed and non-cuffed nasal endotracheal tubes. Prior to using the device, the desired size of the nasal endotracheal tube must be selected and then matched to corresponding Rhinoguard size (large or small). The device is then cut just above the indices (marks) corresponding to the selected endotracheal tube size and connected with the endotracheal tube. Once mated, the distal end of the device is introduced into the naris of choice and gently pushed forward into the oropharynx. Lastly, the distal end of Rhinoguard is grasped and removed from the mouth with the aid of a laryngoscope and McGill forceps.

Intended Use/Indications for Use

The Rhinoguard is a nasal endotracheal tube introducer/dilator designed to allow the passage of a nasal endotracheal tube from the nares to the oropharynx. The device can be used with cuffed and non-cuffed nasal endotracheal tubes.

Technological Characteristics

The device comparison table below provides a general summary of the technological characteristics of the Rhinoguard device compared to the predicate device. The Rhinoguard was classified as a class II device because it is an accessory to class II nasal endotracheal tubes. For this reason, nasal endotracheal tubes were selected as the predicate to the Rhinoguard. Provided that the Rhinoguard is an accessory to nasal endotracheal tubes and to assist with the characterization of certain design features and performance characteristics of the Rhinoguard device, two other class I reference devices (Sun-med Endotracheal Tube Introducer and Pilling Bougie/Dilator) were also selected. The Rhinoguard device is similar in operation to the legally marketed class I reference devices. These similarities between the proposed and reference devices are identified to support safety and efficacy of the introducing and dilating features of the Rhinoguard.

Device Comparison

As explained in detail below, the Rhinoguard is substantially equivalent to other legally marketed Rusch Preformed AGT Nasal Endotracheal Tubes (Cuffed & Uncuffed (K931164 & K931165), Sun-Med Endotracheal Tube Introducer, and Pilling Bougie/Dilator. Specifically, the Rhinoguard is substantially equivalent to the predicate devices identified. Rhinoguard has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate device(s). A substantial equivalence device comparison table comparing the similarities and differences between the Rhinoguard and its predicate and reference device(s) is provided below. Minor differences in the technological characteristics do not raise new questions of safety or efficacy. Performance (bench) testing demonstrates that the Rhinoguard is as safe and effective as its predicate devices. Because the proposed device functions as an accessory to an endotracheal tube, the Rusch Preformed AGT Nasal Endotracheal Tube was selected as the predicate device and supporting devices with introducer/dilator functionalities were selected as reference devices.

Table 5.1 – Device Comparison Table

Device Comparison Table				
	Rhinoguard (Proposed device)	**Rusch Preformed AGT Nasal Endotracheal Tubes (cuffed & uncuffed)** (Predicate Device) *K931164 & K931165*	**Sun-med Endotracheal Tube Introducer** (Reference Device) *Exempt*	**Pilling Bougie/ Dilator** (Reference Device) *Exempt*
FDA Class	Class II	Class II	Class I	Class I
FDA Product Code	BTR	BTR	KCD	KCD
FDA Regulation	868.5730 – Tracheal Tube	868.5730 – Tracheal Tube	874.4420 – Ear, nose, and throat manual surgical instrument	874.4420 – Ear, nose, and throat manual surgical instrument
510k #	N/A	K931164 & K931165	N/A - Class I, 510(k) exempt	N/A - Class I, 510(k) exempt
Indications	Indicated to aid in nasal intubation	Indicated for nasal intubation and for airway management	Indicated to aid in oral intubation	Indicated to aid in oral intubation
User Population	Adult and pediatric	Adult and pediatric	Adult and pediatric	Adult and pediatric
Operating principle	Device mates to tip of nasal endotracheal tube and enters through the nostrils. Device is advanced to the oropharynx and then separated from the endotracheal tube. Device exits the mouth prior to entering trachea.	Device enters though the nostrils and is advanced past the vocal cords and finally placed into the trachea.	Endotracheal tube is inserted over the device. Device enters the trachea prior to the endotracheal tube and then the device is removed after placing the endotracheal tube into the trachea.	Device enters airway and then is removed once airway is dilated.
Enters trachea	No	Yes	Yes	Yes
Maintains an open airway	No	Yes	No	No
Materials	Polyvinyl Chloride (thermoplastic)	Polyvinyl Chloride (thermoplastic)	Low Density Polyethylene (thermoplastic)	Silicone and tungsten
Sterile	Yes (Radiation)	Yes (ETO)	Yes (ETO)	Meant for sterilization by end user
Closed tip	Yes	No	Yes	Yes
Rounded tip	Yes	No	Yes	Yes
Straight or curved	Curved	Curved	Both available (for curved units, curve is just in tip of the device)	Straight
Sizes	Small and large sizes to accommodate nasal endotracheal tube sizes 3.0 – 8.0 mm	3.0 – 8.0 mm	Small and large sizes to accommodate endotracheal tube sizes 4.0 – 11.0 mm	NA – dilates airway rather than mates with tube Sizes available 20 FR – 60 FR

Performance Characteristics

Nonclinical testing was conducted for supporting substantial equivalence between the Rhinoguard and predicate device. The nonclinical tests addressed device performance characteristics such as flexibility, penetration force, biocompatibility, sterilization, packaging and shelf life. In conclusion, the proposed device performed equivalent to or better than the predicate device.

Testing Completed	Testing Description	Standards Referenced
Kink Testing	The purpose of this test was to confirm that the Rhinoguard meets the pre-determined flexibility requirements and that device performance is equivalent to the predicate device.	N/A
Disconnection Testing	The purpose of this test was to confirm that the Rhinoguard meets the pre-determined flexibility requirements and that the device performance is equivalent to the predicate device.	N/A
Perforation Testing	The purpose of this test was to confirm that the Rhinoguard is less of a penetrator than the predicate device.	N/A
Biocompatibility Testing (to include cytotoxicity, systemic toxicity, intracutaneous, maximaization sensitization)	The purpose of this test was to confirm that the Rhinoguard meets pre-determined biocompatibility requirements.	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2006
Sterility Testing (to include bioburden, verification dose, sterility, bacteriostasis/ fungistasis	The purpose of this test was to confirm that the Rhinoguard can be sterilized to a Sterility Assurance Level (SAL) of 1.0×10^{-6}.	ISO 11137-1:2006 ISO 11137-2:2012 ISO 11737-1:2006 ISO 11737-2:1995
Shelf Life Testing (Packaging – to include label retention, seal strength, bubble leak test, package drum test, dye penetration)	The purpose of this test was to confirm that the device packaging functionality and performance is acceptable after the desired shelf life of the product.	ISO 11607-1:2006 ISO 11607-2:2006 D14169-09 F2096-11
Shelf Life Testing (Device – to include kink, disconnection, and perforation)	The purpose of this test was to confirm that the device functionality and performance is acceptable after the desired shelf life of the product.	N/A
Design (Usability) Validation Testing	The purpose of this test was to confirm that the Rhinoguard meets the intended use, user needs, and usability requirements when tested under a simulated use environment.	N/A

All performance testing met acceptance criteria defined in protocols.

Substantial Equivalence – Comparison to Predicate Device

Among the information and summary tables included in this 510(k) submission to support substantial equivalence of the Rhinoguard device to the legally marketed predicate device are: 1.) device description, 2.) indications for use, 3.) device comparison tables, 4.) material information, 5.) nonclinical (bench) test results, and 6.) labeling. In particular, nonclinical test results demonstrate that there were no differences that are critical to the intended use of the proposed device or that affect the safety and effectiveness of the proposed device when used as labeled.

The proposed and predicate devices have the same intended use, in as far as that both are used during nasal intubations, and similar indications, technological characteristics and principles of operation. The proposed device differs from the predicate device in certain design features, which are required to support aiding in nasal intubation (as do the reference devices) rather than in airway management (as does the predicate). The minor differences in technological characteristics have been identified and do not present any new issues of safety or effectiveness. Thus, the Rhinoguard device is substantially equivalent to the Rusch Preformed AGT Nasal Endotracheal Tubes (K931164 & K931165).

(End of Section)