DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 12, 2016

Atos Medical AB
Elin Algotsson
Regulatory Affairs Manager
Kraftgatan 8
Horby, SE-242 22
Sweden

Re: K151404
Trade/Device Name: ProTrach DualCare
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: January 13, 2016
Received: January 15, 2016

Dear Elin Algotsson:

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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151404

Device Name
ProTrach DualCare

Indications for Use *(Describe)*
ProTrach DualCare is a combined Speaking Valve and Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.

In HME-mode the device conditions inhaled air by retaining heat and moisture from the exhaled air.

By turning the lid of the Speaking Valve into speaking mode air is re-directed to enable speech.

The entire device is for single patient use and the HME-part is for single use.

Patient Population: For spontaneously breathing tracheostomized patients (adults and pediatric patients greater than 10kg in weight) using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.

Environment of Use: Hospitals, ICU, sub-acute care institutions and home.

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

Atos Medical AB
P.O Box 183 Tel – 011-46-415 198 00
SE-242 22 Fax – 011-46-415 198 98
Hörby Sweden

Official Contact: Elin Algotsson – Regulatory Affairs Manager

Proprietary or Trade Name: ProTrach DualCare

Common/Usual Name: Speaking Valve

Classification Class II - 21 CFR 868.5800

Classification Name/Code: JOH – Tracheotomy Tube and Tube Cuff

Device: ProTrach DualCare

Predicate Devices: Fogless International AB - SPIRO Speaking Valve – (K122932)

Passy-Muir Inc.- Passy Muir Speaking Valves – (K944451) (for reference)
Engineered Medical Systems - TrachVox – (K013728) (for reference)
Atos Medical – Provox FreeHands HME – (K022125) (for reference)

Device Description:

The Speaking Valve, the HME DigiTop and the HME DigiTop O2 (sold separately) are all used to enable speaking. They will therefore be referenced to as “speaking devices”.

Speaking Valve and HME 15 / 22
The reusable Speaking Valve is used with a single use 15 mm or 22 mm Heat and Moisture Exchanger (HME). The HME is placed so that it prevents direct contact between the Speaking Valve and the airways. This prevents the Speaking Valve from being clogged or soiled by mucus.

The Speaking Valve has two modes: speaking mode and HME mode.

In speaking mode, a flexible membrane is positioned in the airflow openings and acts as a one way valve. It opens during inhalation so the patient can inhale through the device. During exhalation, the membrane remains closed and the air is re-directed through the upper airways and the vocal folds. Thereby the patient is able to speak. In speaking mode the inhaled air does not get conditioned since the exhaled air goes out through the upper airways.

In HME mode the membrane is moved out of the way of the airflow so that the patient both inhales and exhales through the device. The inhaled air is conditioned by the heat and moisture that is retained from the exhaled air in the impregnated HME media. In HME mode, speaking is not possible. The device is switched between the modes by rotating the lid of the Speaking Valve until it clicks into the desired position.

HME DigiTop and HME DigiTop O2
The HME DigiTop and the HME DigiTop O2 enable use of the HME without the Speaking Valve, and can manually be occluded to enable speaking.

Indications for Use:

ProTrach DualCare is a combined Speaking Valve and Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.

In HME-mode the device conditions inhaled air by retaining heat and moisture from the exhaled air.

By turning the lid of the Speaking Valve into speaking mode air is re-directed to enable speech.

The entire device is for single patient use and the HME-part is for single use.

Patient Population: For spontaneously breathing tracheostomized patients (adults and pediatric patients greater than 10kg in weight) using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.

Environment of Use:
Environments of use include; Hospitals, ICU, sub-acute care institutions and home.

Substantial Equivalence Comparison to Predicates

There are no significant differences between the ProTrach DualCare compared to the predicate device in terms of indications, materials, design and operating principles as summarized below.

Attributes of predicate (SPIRO Speaking Valve)	**ProTrach DualCare HME 15 Regular**	**ProTrach DualCare HME 15 XtraMoist**	**ProTrach DualCare HME 22**
Indication for use: For spontaneous breathing tracheotomy patients.	Same	Same	Same
Environment of use: Hospitals, ICU, sub-acute care institutions and home	Same	Same	Same
Patient population: Conscious patients, trained to use the speech valve by qualified staff.	Same (Intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff. Contraindicated for unresponsive or sedated patients.)		
Technology and Operating principle: Eliminates the necessity of finger occlusion for the patient with a tracheostomy tube.	Same	Same	Same
Incorporated speech valve	Same	Same	Same
Provides heat and humidity (moisture loss: 28 mgH_2O/l air)	Better humidification: 22 mgH_2O/l air	Better humidification: 20 mgH_2O/l air	Better humidification: 21 mgH_2O/l air
Dead space: 5.6 ml	4.05 ml (dead space does not raise concern because the dead space is less than predicate)	4.05 ml (dead space does not raise concern because the dead space is less than predicate)	4.62 ml (dead space does not raise concern because the dead space is less than predicate)
Dimensions (mm): Outer diameter: 26.9 Inner diameter: 25.5	27.6 20.8-22.9	27.6 20.8-22.9	27.6 21.1-22.9

Height (contributing to dead space) 11.8 Height (total): 26.9	11.9 26.1	11.9 26.1	13.35 15.2
Can provide supplemental oxygen through oxygen connector	Same	Same	Same
Intended to connect to tracheostomy tube of spontaneously breathing patient	Same	Same	Same
Intended for single patient use	Same	Same	Same
HME exchanged at least every 24 h.	Same	Same	Same
Prescription use	Same	Same	Same
Standard 15/22 mm connectors	Same (15 mm connector)	Same (15 mm connector)	Same (22 mm connector)
Speech valve one-way closed position, always open for inhalation	Same	Same	Same
Allows exhalation to atmosphere freely	Similar for all versions of the device. The DualCare allows the user to switch between speaking mode and HME mode by turning the lid of the device. In speaking mode the exhaled air is directed via the upper airways and vocal folds whereas in HME mode the exhaled air is directed out of the tracheostoma.		
Contraindications: Unconscious and/or Comatose Patients	Same	Same	Same
Inflated Tracheostomy Tube Cuff	Same	Same	Same
Foam Filled Cuffed Tracheostomy Tube	Same	Same	Same
Severe Airway Obstruction Which May Prevent Sufficient Exhalation	Same	Same	Same
Thick and Copious Secretions	Same	Same	Same
Severely Reduced Lung Elasticity That May Cause Air Trapping	Same	Same	Same
This Device Is Not intended For Use With Endotracheal Tubes	Same	Same	Same
Materials: Materials HME: Calcium chloride treated polyurethane foam	Same. The materials included have been assessed for biocompatibility in accordance with the ISO 10993 series and have demonstrated acceptable results.	Same. The materials included have been assessed for biocompatibility in accordance with the ISO 10993 series and have demonstrated acceptable results.	Same. The materials included have been assessed for biocompatibility in accordance with the ISO 10993 series and have demonstrated acceptable results.
Materials Speaking Valve: Silicone and plastic	Same. The materials included have been assessed for biocompatibility in accordance with the ISO 10993 series and have demonstrated acceptable results.	Same. The materials included have been assessed for biocompatibility in accordance with the ISO 10993 series and have demonstrated acceptable	Same. The materials included have been assessed for biocompatibility in accordance with the ISO 10993 series and have demonstrated acceptable

		results.	results.
Clinical claims in labeling and supporting evidence: Make the function of speech easier.	Same	Same	Same
The filter and Speaking valve are not affected by secretions during coughing.	Same in speaking mode. In HME mode the filter acts as a barrier preventing the speaking valve from being affected by secretion.	Same in speaking mode. In HME mode the filter acts as a barrier preventing the speaking valve from being affected by secretion.	Same in speaking mode. In HME mode the filter acts as a barrier preventing the speaking valve from being affected by secretion.

The differences noted in the table above are addressed by the testing summarized below:

Summary of Non-Clinical Testing:

The following tests were performed to verify that ProTrach DualCare met applicable safety and performance requirements.

The main focus areas of testing were:

- Verification of the moisture loss, airflow resistance, leakage test and dead space.
- Verification of attachment and detachment forces in the different interfaces including the durability of the devices.
- Simulated use of all DualCare products and their Instructions for use.
- Verification of DualCare Warning label durability.
- Verification of DualCare products' function after drop test, fatigue test, climate testing, aging and transport.
- Biocompatibility: The proposed device was classified as a Surface device with indirect contact with mucosal membranes via air. Duration: Permanent (>30 days).
  The following tests were conducted in accordance with the ISO 10993 series and rendered acceptable biocompatibility results:
  - cytotoxicity,
  - sensitization,
  - intracutaneous reactivity,
  - acute systemic toxicity
  - genotoxicity
  - Leachables & Extractables quantitative and qualitative testing

In addition, risk management according ISO 14971 and simulated use testing (usability study) has been conducted.

Substantial Equivalence Conclusion:

Based on the comparison information and non-clinical performance testing Atos Medical AB concludes that the ProTrach DualCare is as safe, as effective, and performs as well as or better than the predicate. ProTrach DualCare is therefore considered to be substantially equivalent to the predicate device.