DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 21, 2016

TRACOE medical GmbH
Eva Schaeffer
Head of Quality
Reichelsheimer Straße 1/3
55268 Nieder-Olm
Germany

Re: K152865
Trade/Device Name: TRACOE® smart Cuff Manager
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: August 21, 2015
Received: August 26, 2016

Dear Eva Schaeffer:

This letter corrects our substantially equivalent letter of September 27, 2016.

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" (21CFR 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152865

Device Name
TRACOE® smart Cuff Manager

Indications for Use *(Describe)*

The TRACOE® smart Cuff Manager is intended to maintain the HVLP (high volume low pressure) cuff pressure, of an endotracheal tube or tracheostomy tube, within the range of 20 to 30 cm H20 through passive control.

It is for single patient use, and indicated for mechanically ventilated or spontaneously breathing patients. It is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics and is suitable for inter- or intra-facility transport.

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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510(K) SUMMARY
as required by section 21 CFR 807.92

Date: September 26, 2016

Submitter of 510(k):

Company name: TRACOE medical GmbH
Establishment Registration number: 8010485
Address: Reichelsheimer Str. 1/3
55268 Nieder-Olm
Germany
Phone: (+49)61369169-0
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Correspondent: Eva Schaeffer
Head of Quality

Device Name:

Trade/Proprietary Name: TRACOE® smart Cuff Manager
Common/Usual Name: Cuff, tracheal tube, inflatable
Classification: Class II
Classification Name: Inflatable tracheal tube cuff
(21 CFR 868.5750, Product Code: BSK)

Legally Marketed Devices

Our device is based on the legally marketed devices cited in the table below:

Manufacturer	Device	Product Code	510(k) #
Smith Medical Inc.	PressureEasy Cuff Pressure Controller	BSK	K833327
Covidien	Model GV-10 Lanz Pressure Valve	BTR	K791045

Device Description:

The TRACOE® smart Cuff Manager is an accessory device for high volume low pressure (HVLP) cuffed endotracheal/tracheostomy tubes to maintain the cuff pressure within a range of 20 cm H_2O to 30 cm H_2O. This device includes a spherical, hard shell (transparent) outer casing with an elastic inner balloon (blue), that is attached to a base housing with both a male and female luer connector. The male connector is inserted into the inflation line (pilot balloon valve of the endotracheal/tracheostomy tube HVLP cuff) and the female connector is attached to a cuff inflation device (syringe or cuff pressure monitor). When the TRACOE® smart Cuff Manager is connected to the cuff inflation line the inner balloon is inflated with a cuff inflation device until the balloon diameter is between 2/3 - 3/4 of the outer casing. The cuff inflation device is then removed from the TRACOE® smart Cuff Manager, and after a few minutes the cuff pressure is rechecked to confirm the cuff is properly inflated. The inflated inner balloon of the TRACOE® smart Cuff Manager will act as a pressure reservoir, allowing the air to flow between the balloon and the endotracheal/tracheostomy cuff, through passive control, in order to maintain the pressure range.

When the endotracheal/tracheostomy tube cuff pressure increases, due to compression through patient motion, coughing etc., the surplus air flows slowly into the inner balloon of the TRACOE® smart Cuff Manager through the integrated damping function. The damping function prevents sudden changes in cuff pressure which could result in a gap between the cuff and the trachea. When the cuff pressure is reduced (following the patient motion) the inner balloon will allow the stored air to freely flow (without damping) back into the endotracheal/tracheostomy tube cuff in order to reinstate the cuff pressure to the prescribed range of 20 cm H_2O to 30 cm H_2O.

The TRACOE® smart Cuff Manager is for single patient use, and provided sterile for ease of use when connecting in a sterile environment. The device is applicable for mechanically ventilated or spontaneously breathing patients under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics and is suitable for inter- or intra-facility transport.

Intended use:
The TRACOE® smart Cuff Manager is intended to maintain the HVLP (high volume low pressure) cuff pressure, of an endotracheal tube or tracheostomy tube, within the range of 20 to 30 cm H20 through passive control.

It is for single patient use, and indicated for mechanically ventilated or spontaneously breathing patients. It is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics and is suitable for inter- or intra-facility transport.

Summary of the Technical Characteristics

For substantial equivalence, the predicate devices K833327 PressureEasy and K791045 Lanz were selected based on their intended use and similarity in design and functionality.

	TRACOE® smart Cuff Manager	Smith Medical Inc. PressureEasy Cuff Pressure Controller (Radionics)	Covidien Model GV-10 Lanz Pressure Valve (Lanz)
Intended Use	To maintain the HVLP (high volume low pressure) cuff pressure, of an endotracheal tube or tracheostomy tube, within the range of 20 to 30 cm H2O through passive control.	To maintain the HVLP (high volume low pressure) cuff pressure, of an endotracheal tube within the range of 20 to 30 cm H2O through passive control.	To maintain the HVLP (high volume low pressure) cuff pressure, of an endotracheal tube or tracheostomy tube, within the range of 25 to 33 cm H2O through passive control.
Device Classification	2	2	2
510k Number	K152865	K833327	K791045
Classification Product Code	BSK	BSK	BTR
Regulation Number	868.5750	868.5750	868.5730
Patient Population			
Patients requiring a High volume low pressure cuffed endotracheal tube	Yes	Yes	Yes
Patients requiring a High volume low pressure cuffed tracheostomy tube	Yes	No	Yes

Patients requiring mechanical ventilation	Yes	Yes	Yes
Spontaneous breathing patients	Yes	Yes	Yes
Patients under medical supervision in hospitals, pre-hospitals, emergency rooms (ER), extended care facilities, outpatient clinics	Yes	Yes	Yes
Technical Characteristics			
Type of control	Passive	Passive	Passive
Cuff pressure range	20 cm H2O to 30 cm H2O	20 cm H2O to 30 cm H2O	25 cm H2O to 33 cm H2O
Internal pressure reservoir (balloon)	Elastic inner balloon that expands and contracts as air flows to and from the cuff	Elastic inner balloon that expands and contracts as air flows to and from the cuff	Elastic inner balloon that expands and contracts as air flows to and from the cuff
Visual pressure range	Blue inner balloon diameter	Green stripe	Beige inner balloon diameter
Damping function of air flow from cuff to the balloon	Yes	No	Yes
Free flow of air from the balloon to the cuff	Yes	Yes	Yes
Cuff pressure is maintained when the device is disconnected.	Yes	Yes	No
Inflation via female luer connector	Yes	Yes	Yes
Inflation by syringe or cuff pressure monitor	Yes	Yes	Yes
Connection to inflation line of cuff	Yes	Yes	Yes
Single patient use	Yes	Yes	Yes
Patient contact:	Skin surface	Skin surface	Skin surface
Provided sterile	Yes	No	Yes

The TRACOE® smart Cuff Manager intended use represents a combination of the predicate devices intended use, therefore any differences in the intended use are not considered critical and do not affect the safety and effectiveness of the device. The similarities in design and technology are the basis and reason for substantial equivalence of the TRACOE® smart Cuff Manager to the legally marketed predicate devices.

Summary of Non- clinical testing

Performance and mechanical testing was performed with clear acceptance criteria that addressed design, performance, and functionality of the device. In addition, predicate device comparison testing was performed which demonstrated substantial equivalence between the TRACOE® smart Cuff Manager to the legally marketed predicate devices. This testing included:

- Sterilization and Packaging Validation in accordance with ISO 1135-1 and ISO 10993-7.
- Intra and inter-facility transportation testing includes shock and vibration testing, external pressure and temperature testing while maintaining the cuff pressure range (20 cm H_2O to 30 cm H_2O).
- Mechanical testing confirmed luer connections, pressure reservoir filling, damping function and maintaining the cuff pressure range (20 cm H_2O to 30 cm H_2O) under multiple situations (e.g. extended time periods, cuff compression).
- Comparison testing with the predicate devices PressureEasy (K833327) and Lanz (K791045) included maintaining the cuff pressure during volume/pressure changes and over an extended period of time.

The results of this testing demonstrated that the TRACOE® smart Cuff Manager is substantially equivalent to the legally cleared predicate devices.

Summary of Clinical testing

Clinical testing was not required to demonstrate substantial equivalence.

Conclusion

The TRACOE® smart Cuff Manager has passed all defined criteria. The device has performed as well or better than the predicate devices and is therefore considered substantially equivalent to the cleared predicate devices.