DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 21, 2016

TRACOE Medical GmbH
Eva Schaeffer
Head of Quality
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Nieder-Olm
Rheinland-Pfalz, D-55268
Germany

Re: K152778
Trade/Device Name: TRACOE® cuff pressure monitor
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: November 15, 2016
Received: November 18, 2016

Dear Eva Schaeffer:

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

Tina Kiang, Ph.D.
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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)*
K152778

Device Name
TRACOE® cuff pressure monitor

Indications for Use *(Describe)*
The TRACOE® cuff pressure monitor (cpm) is a hand-held manometer intended for checking cuff pressure and inflating the cuff of high-volume-low-pressure cuffed endotracheal tubes or tracheostomy tubes.

Patient Population: Adult, pediatric, neonatal patients who have high-volume-low-pressure cuffed endotracheal/ tracheostomy 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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510(K) SUMMARY
as required by section 21 CFR 807.92

Date:	December 21, 2016
Submitter of 510(k):	
Company name:	TRACOE medical GmbH
Establishment Registration number:	8010485
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Correspondent:	Eva Schaeffer Head of Quality

Device Name:

Trade/Proprietary Name:	TRACOE® cuff pressure monitor
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 device cited in the table below:

Manufacturer	Device	Product Code	510(k) #
RUSCH	Endotest Cuff Pressure Monitor	BSK	K951046

Device Description:

The TRACOE® cuff pressure monitor (cpm) inflates or measures the intra-cuff pressure in the range of 20 – 100 cmH_2O. It is intended for endotracheal or tracheostomy tubes with high-volume low-pressure (HVLP) cuffs.

The cpm consists of a pressure gauge/manometer and a bulb. Between the manometer and the bulb is a male Luer connector air outlet which is connected to the inflation line (pilot balloon valve) of the endotracheal/tracheostomy tube HVLP cuff. Opposite the Luer connector is an integrated air release valve that can be opened and closed with a knurled screw.

To inflate the HVLP cuff, the male Luer connector of the cpm is inserted into the inflation line (pilot balloon valve) of the endotracheal/tracheostomy tube, HVLP cuff and the knurled screw is closed, the bulb is then squeezed to inflate the HVLP cuff. As the pressure increases in the HVLP cuff the pressure value is displayed on the manometer. Once the cuff is inflated to the required cuff pressure the cpm is disconnected from the inflation line (pilot balloon valve).

To measure the HVLP cuff pressure, the knurled screw is closed and the male Luer connector is inserted into the open end of the cuff inflation line. The manometer will display the current HVLP cuff pressure. If the pressure is too low the bulb can be squeezed to inflate the cuff, or if the pressure is too high the knurled screw can be opened to release the cuff pressure. Once the required cuff pressure is achieved

the cpm is disconnected from the inflation line (pilot balloon valve).

The TRACOE® cuff pressure monitor can be used for adult, pediatric, and neonatal patients. It is re-usable and provided non-sterile. A sterile connection tube (REF 702, 1.0 m) is supplied with the TRACOE® cpm which provides an extension tube for inflating or measuring cuff pressure. The TRACOE® cuff pressure monitor is not suitable for continuous monitoring of HVLP cuff pressure.

Intended use:

The TRACOE® cuff pressure monitor (cpm) is a hand-held manometer intended for checking cuff pressure and inflating the cuff of a high-volume low-pressure cuffed endotracheal tubes or tracheostomy tubes.

Patient Population: Adult, pediatric, neonatal patients who have high-volume-low-pressure cuffed endotracheal/tracheostomy tubes.

Summary of the Technical Characteristics

For substantial equivalence, the predicate device, Endotest Cuff Pressure Monitor (K951046) was selected based on its intended use and similarity in design and functionality.

	TRACOE® cuff pressure monitor (cpm)	RUSCH Endotest Cuff Pressure Monitor
Intended Use	The TRACOE® cuff pressure monitor (cpm) is a hand-held manometer intended for checking cuff pressure and inflating the cuff of a high-volume low-pressure cuffed endotracheal tubes or tracheostomy tubes. Patient Population: Adult, pediatric, neonatal patients who have high-volume-low-pressure cuffed endotracheal/ tracheostomy tubes.	The Endotest is a cuff pressure measuring device to monitor the filling of low pressure. The Endotest device is used to fill and empty the low-pressure cuffs of tracheal tubes, tracheostomy cannulas, bronchial tubes, and laryngeal masks. It is also used for the intermittent monitoring of the cuff pressure during the time of intubation.
Device Classification	2	2
510k Number	K152778	K951046
Classification Product Code	BSK	BSK
Regulation Number	868.5750	868.5750
Patient Population		
Patients requiring a high volume low pressure (HVLP) cuffed endotracheal tube	Yes	Yes
Patients requiring a high volume low pressure (HVLP) cuffed tracheostomy tube	Yes	No
Neonatal, pediatric or adult patients	Yes	Yes

Prescription Use	Yes	Yes
Technical Characteristics		
Mode of operation	Manual	Manual
Cuff pressure range	20 to 100 cm H_2O	0 to 120 cm H_2O
Hand Air pump (balloon)	Compression of the rubber bulb inflates the HPLV cuff	Compression of the rubber bulb inflates the HPLV cuff
Visual pressure range	Manometer	Manometer
Displays cuff inflation pressure	Yes	Yes
Ability to inflate or deflate HPLV cuff	Yes	Yes
Connects to HPLV cuff inflation line (Pilot)	Yes	Yes
Inflation via male Luer connector	Yes	Yes
Valve to release cuff pressure	Yes	Yes
Reusable device (Not for single use or single patient use only)	Yes	Yes

The TRACOE® cuff pressure monitor intended use is similar to the predicate device. This difference in the intended use is not considered critical and does not affect the safety and effectiveness of the device:

Difference	Assessment
In addition to the cpm, the Predicate Device can also be used for bronchial tubes and laryngeal masks.	The reduced intended use of the TRACOE® cpm does not affect the safety or effectiveness in endotracheal and tracheostomy tubes.
The Predicate Device claims accuracy over a larger pressure range.	The pressure range claimed for the TRACOE® cpm includes the clinically relevant range of 20 – 30 cmH_2O.

The similarities in design and technology are the basis and reason for substantial equivalence of the TRACOE® cuff pressure monitor 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® cuff pressure monitor to the legally marketed predicate devices. This testing included:

- Mechanical testing confirmed Luer connections in accordance with ISO 594-1
- Bench testing included cuff filling, pressure accuracy, and the ability to maintain pressure.
- Comparison testing with the predicate device, Endotest (K951046), included accuracy of pressure readings
- Connection tube: sterilization (including sterilant residuals), simulated distribution and packaging validation in accordance with ISO 11135, ISO 11607-1, ISO 11737-1 and ISO 10993-7.
- The device has been validated to a pressure range of 20 - 100 cm H_2O.

The results of the non-clinical testing demonstrate that the TRACOE® cuff pressure monitor is

substantially equivalent to the legally cleared predicate device.

Summary of Clinical testing

Clinical testing was not required to demonstrate substantial equivalence.

Conclusion

The TRACOE® cuff pressure monitor has passed all defined criteria. The device has performed as well or better than the predicate device and is therefore considered substantially equivalent to the cleared predicate device.