August 5, 2021

TRACOE medical GmbH
% Lu Anne Bauer
President
Capamed Inc.
14 E. Eau Claire Street Unit 447
Rice Lake, Wisconsin 54868

Re: K203362
Trade/Device Name: TRACOE vario
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: July 8, 2021
Received: July 9, 2021

Dear Lu Anne Bauer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203362

Device Name
TRACOE® vario

Indications for Use *(Describe)*
TRACOE® vario tracheostomy tubes are indicated for providing tracheal access for airway management especially to those patients with unusual anatomy or patients with thick necks. lt may be used for up to 29 days.

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: November 11, 2020

Submitter of 510(k):

Company name:	TRACOE medical GmbH
Establishment Registration number:	8010485
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Correspondent:	Dr. Katharina Schrick Head of Regulatory Affairs

Device Name:

Trade/Proprietary Name:	TRACOE® *vario*
Common/Usual Name:	Tracheostomy Tubes
Classification	Class II
Classification Name:	Tracheostomy tube and tube cuff 21 CFR 868.5800 Product Code: JOH

Legally Marketed Device

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

Manufacturer	Device	510(k) #
TRACOE medical GmbH	*vario* Tracheostomy Tubes	K051587

Device Description:
TRACOE® *vario* Tracheostomy Tubes are suitable for adults and adolescents (12-21 years) where access to the airway via a tracheostoma is required. The flexible tracheostomy tubes are single patient use, individually packaged with an obturator and neckstrap and provided sterile.

The TRACOE® *vario* Tracheostomy Tubes have an adjustable neck flange with a locking mechanism that allows the length of the tube to be adapted to the anatomical requirements of the individual patient. In addition, the neck flange includes two flexible wings that allow the fastening of a strap around the patients neck for fixation of the tracheostomy tube. These wings can be turned together around the flange or rotated independently within a range of about 60° to 180°. These features are useful for patients with thick necks or with unusual anatomy. The TRACOE® *vario* Tracheostomy Tubes are available in different models: with or without a high-volume low-pressure cuff, with or without a

subglottic suction line which is suitable for Above Cuff Vocalization, fenestrated tube, standard or extended lengths, different diameters, with or without a Minimally Traumatic Insertion System (P series) and can be used within an MR environment.
The TRACOE® *vario* Tracheostomy Tube is for prescription use only and is applicable for mechanically ventilated or self-breathing patients in hospitals, pre-hospital (EMS), extended care facilities, outpatient clinics and can be used by individuals trained in tracheostomy care.

Intended use:
TRACOE® *vario* Tracheostomy Tubes are indicated for providing tracheal access for airway management especially to those patients with unusual anatomy or patients with thick necks. It may be used for up to 29 days.

Summary of the Technical Characteristics

This submission reflects modifications to the current legally marketed TRACOE® *vario* Tracheostomy Tube (K051587) therefore the overall design and functionality are identical. The following table represents an overview of the TRACOE® *vario* Tracheostomy Tube technical characteristics.

	TRACOE® *vario* Tracheostomy Tube K203362	TRACOE® *vario* Tracheostomy Tube K051587
Available models (diameters)	06,07,08,09,10,11	
Available lengths	70, 80, 90, 100, 110 mm XL lengths: 104, 123, 126, 135mm	70, 80, 90, 100, 110mm
Tube design	• Available with a bending angle of 100° • Flexible Tube (cannula) with a 15 mm connector • Available with a spiral reinforced tube or an x-ray contrast line • Available with and without a high-volume low-pressure cuff • Available with or without a subglottic suction line	
	• Fenestrated model available	Not available
Neck Flange	• An adjustable neck flange that allows shifting of tube axis with a locking mechanism to prevent tube movement after placement • Flexible wings of the neck flange can be adjusted individually or together at different angles for improved fixation	
Accessories	• Wide neck strap • Obturator	
	• P Series: Minimally Traumatic Insertion System	Not available
Material	Tracheostomy tube -Cannula	PVC
	Subglottic suction line	PVC
	Subglottic suctioning port	PVC
	Adjustable Neck Flange	Polysuflone, Polypropylene, Polyacetal
	Flexible wings	Polypropylene
	15 mm connector end	Polystyrene

	HVLP-Cuff	PVC
	Obturator	Polyethylene
	Neck strap	Nylon, Polyester Velcro closure
	Minimally Insertion System • Inserter: Thermoplastic Polyurethane • Guiding catheter: Thermoplastic Polyurethane • Silicone Sleeve: Silicone, BaSO4	Not available

The TRACOE® *vario* Tracheostomy Tubes in this submission are the same devices included in the original 510(k). Therefore, the differences are limited to modification to the design and improved usability which include:

- The addition of a fenestrated model (REF 464)
- Additional tracheostomy tube lengths (XL models)
- Addition of TRACOE® *vario* Tracheostomy Tube with a Minimally Traumatic Insertion System (P series only)
- An expanded intended use statement to include useful life (29 days)
- A change in product code (JOH) to reflect both the cuffed and uncuffed models (original 510(k) product code was BTO)
- Updated product labeling to include clinical use of the device within an MR environment and use of the subglottic suction line for Above Cuff Vocalization (ACV)

These differences do not affect the principal technology, safety, effectiveness, function, and operational characteristics of the devices. Since there has been no change in the overall design, material, or technology of the TRACOE® *vario* Tracheostomy Tube the device is considered substantially equivalent to the legally marketed predicate device.

Summary of Non- clinical testing

TRACOE® *vario* Tracheostomy Tubes functionality and performance were tested based on the product requirements and identified control measures from the risk management process. The testing was performed with defined test cases and clear acceptance criteria. This testing included: bench testing, functional testing, testing requirements from recognized standards, cleaning and sterilization, shelf-life, transport, and biocompatibility with testing performed both in house and by accredited 3rd party laboratories. This testing included:

Sterilization and Cleaning: TRACOE® *vario* Tracheostomy Tube sterilization validation was performed in accordance with ISO 10993-7, ISO 11135, ISO 11737-1 which confirm that the allowable bioburden, sterility assurance level of 10^{-6} was achieved and the ethylene oxide residues and ethylene chlorohydrin residues are below the committed limit after the quarantine and desorption time. The cleaning validation, including cytotoxicity testing (ISO 10993-5:2009), was performed and confirmed that the cleaning methods, provided to the users, do not affect product functionality, meet the requirements, and are considered non-cytotoxic.

Shelf Life and Transport Testing: The TRACOE® *vario* Tracheostomy Tube and associated packaging was tested in accordance with ASTM F 1980-16, ASTM 1886/F1886M, ASTM F1929-15, ASTM F2096-11, ASTM F88/88M, ISO 11607-1, ISO 18190 and ISO 14644-1. This testing included shelf life testing

performed through accelerated aging which confirmed the sterile packaging performs as intended with a 5 year shelf life. Transport simulation testing was performed in accordance with ASTM D4169-16 which confirmed that the TRACOE® *vario* Tracheostomy Tubes, including the associated packaging, is not affected by product shipment and performs as intended.

Biocompatibility Testing: The TRACOE® *vario* Tracheostomy Tubes, including the Minimally Traumatic Insertion System, are the same in material, processing, and functionality as TRACOE legally US marketed devices. The results of the testing, in addition to clinical experience, confirm TRACOE® *vario* Tracheostomy Tubes are made from biocompatible materials, which can be provided sterile and are safe for clinical use.

Bench Testing: Functionality testing of the TRACOE® *vario* Tracheostomy Tubes was performed in accordance ISO 5366, and ISO 5356-1. This testing encompassed the TRACOE® *vario* Tracheostomy Tube product range including XL models, fenestrated models, and the Minimally Traumatic Insertion System (P models). In addition, validation was performed to confirm the use of the subglottic suction line for Above Cuff Vocalization and product labeling was in accordance with ISO 5366 and ISO 15223-1. The results of this testing confirm that the TRACOE® *vario* Tracheostomy Tubes perform as intended, the product information is complete and comprehensive, and the device meets the requirements. Radiopacity testing was performed in accordance ASTM F640-12 and an MRI analysis was performed in accordance with ASTM F2052-15, ASTM F2213-17, ASTM F2119-07, ASTM F2182-11a. The results of the testing confirmed that the TRACOE® *vario* Tracheostomy Tubes are appropriate for radiographic imaging and identified for use in an MR environment. The devices and product labeling clearly identify the MR status of the device in accordance with ASTM F2503-13.

The results of the testing, provided in this submission, adequately demonstrates that the TRACOE® *vario* Tracheostomy Tubes perform as defined in the requirements, in accordance with the recognized consensus standards and meet clinical expectations.

Summary of Clinical testing
Clinical testing of the TRACOE® *vario* Tracheostomy Tube was not required to demonstrate substantial equivalence.

Conclusion
The TRACOE® *vario* Tracheostomy Tube has passed all defined criteria. The device has performed as well as the predicate device and is therefore considered substantially equivalent to the cleared predicate device.