April 27, 2018

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

Re: K172720
Trade/Device Name: TRACOE silcosoft
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: March 29, 2018
Received: March 30, 2018

Dear Lu Anne Johnson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172720

Device Name
TRACOE silcosoft®

Indications for Use *(Describe)*
The TRACOE silcosoft® tracheostomy tube is intended to provide direct airway access for a tracheotomized patient up to 29 days. It may be reprocessed for single patient use up to 7 times.
Patient population: Neonates, infants, children, and adolescents.

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: April 24, 2018

Submitter of 510(k):

Company name:	TRACOE medical GmbH
Establishment Registration number:	8010485
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Correspondent:	Julia Vogler Head of Regulatory Affairs

Device Name:

Trade/Proprietary Name:	TRACOE silcosoft®
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) #
Smiths Medical	Bivona® Tracheostomy Tubes	K083641

Device Description:
TRACOE silcosoft® is a silicone tracheostomy tube, with wire reinforcement, that provides an artificial airway to the lower respiratory tract for neonates, infants, children, and adolescents.

The TRACOE silcosoft® includes a tracheostomy tube, an obturator, a fabric neck strap and a disconnection wedge which are supplied in a sterile blister pack. The silicone tracheostomy tube is radiopaque, available in different diameters and lengths, cuffed or uncuffed models, and includes a plastic or metal obturator. The appropriate diameter and length of the tube is determined by the physician.

For insertion, the neck is extended with the tracheostoma open and free of obstruction. The tracheostomy tube (with the obturator inside), is inserted directly into the tracheostoma until the neck plate is in contact with the skin surface. Once in place the obturator is removed and when applicable, the cuff is filled with sterile water. When the tracheostomy tube is in position, the device is secured with a neck strap.

The TRACOE silcosoft® is intended for single-patient use up to 29 days and may be reprocessed 7 times within this period. The device is applicable for mechanically ventilated or spontaneously breathing patients in hospitals, pre-hospital (EMS), extended care facilities, outpatient clinics, or home care and can be used by individuals trained in tracheostomy care.

Intended use:
The TRACOE silcosoft® tracheostomy tube is intended to provide direct airway access for a tracheostomized patient up to 29 days. It may be reprocessed for single patient use up to 7 times.

Patient population: neonates, infants, children, and adolescents.

Summary of the Technical Characteristics

For substantial equivalence, the predicate device K083641 Bivona® Tracheostomy Tube was selected based on its intended use, design and functionality.

	TRACOE® silcosoft	Bivona® Tracheostomy Tubes K083641
Intended Use	The TRACOE silcosoft® tracheostomy tube is intended to provide direct airway access for a tracheostomized patient up to 29 days. It may be reprocessed for single patient use up to 7 times. Patient population: neonates, infants, children and adolescents.	The Bivona® Tracheostomy Tube is intended to provide direct airway access for a tracheotomized patient for up to 29 days. It may be reprocessed for single-patient use up to 10 times for adult sizes and up to 5 times for pediatric sizes.
Technical Characteristics		
The device is available in LVHP(H_2O) cuffed and uncuffed models with diameters (ID) of 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm	Same	Same
The device is radiopaque and can be used in x-ray, CT or MR imaging (MR Conditional)	Same	Same
The device is provided sterile and intended for single patient use.	Same	Same
The device is inserted into a tracheastoma for less than 29 days and can be reprocessed.	Same	Same
The device is secured with a fabric tie/strap	Same	Same
The tube is made of silicone with wire reinforcement	Same	Same

The tube includes an obturator to assist with insertion	Same	Same
The flange, cuff and inflation system is made of silicone.	Same	Same

The TRACOE silcosoft® and the predicate device have the same intended use, design and functionality. The difference between TRACOE silcosoft® and the predicate device are:

- Patient population: Bivona® offers tracheostomy tubes for adults (larger diameters)
- Reprocessing: Biovona® allows 5 times for pediatrics within 29 days and TRACOE silcosoft® allows 7 times within 29 days.

These differences do not raise different questions of safety and effectiveness of the device. The similarities in design and technology are the basis and reason for substantial equivalence of the TRACOE silcosoft® to the legally marketed predicate device.

Summary of Non- clinical testing

TRACOE silcosoft® has been fully tested to meet the product requirements and identified control measures from the risk management process. This testing included functional testing, testing of recognized standards, sterility and biocompatibility. Testing has been performed both in house and by accredited 3rd party laboratories. This testing included:

- Functional/mechanical testing according to ISO 5366 Anaesthetic and respiratory equipment -- tracheostomy tubes -- part 3: pediatric tracheostomy tubes
- Comprehensive biocompatibility testing was performed based on ISO 10993-1 Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. This test process included a biological risk assessment and chemical analysis, cytotoxicity, genotoxicity, intracutaneous reactivity, sensitization, and acute toxicity
- Sterilization, Reprocessing and Packaging Validation was performed in accordance with ISO 11135-1, ISO 10993-7, ISO 17665-1, ISO 17665-2, and ISO 11138-3.

In addition, a comprehensive comparison testing was performed between the TRACOE silcosoft® and the legally marketed predicate device, Bivona®Tracheostomy Tubes that included design, functionality and performance testing. The successful results of the non-clinical testing demonstrated that TRACOE silcosoft® is substantially equivalent to the predicate device.

Summary of Clinical testing

Clinical testing was not required to demonstrate substantial equivalence.

Conclusion

The TRACOE silcosoft® 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.