VITALTEC CORPORATION
No.12, Lane 4-30, Chyuan Zhou Rd., Hou Li Hsiang, Taichung, 42142, Taiwan, ROC
Tel: 886-4-25580886 Fax: 886-4-25568632
Email: info@vitaltec.com.tw

5. 510(K) SUMMARY (as required by 807.92(c))

JUN 11 2010

K100480

DATE OF SUBMISSION: January 27, 2010

SUBMITTER:
president, Mr. Joseph Chang
VITALTEC CORPORATION
No. 12, Lane 4-30, Chyuan Zhou Rd.,
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ESTABLISHMENT REGISTRATION NO: 3003851906

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TRADE NAME: VITALTEC Rota-Trach Tracheostomy Tube

COMMON/USUAL NAME: Tracheostomy Tube

CLASSIFICATION NAME: Tube, Tracheostomy (W/Wo connector)

CLASSIFICATION PANEL: BTO, Class II, 868.5800

PREDICATED DEVICE: Medical Tracheostomy Tubes; 510K No. (K031553)

INTENDED USE: Tracheostomy Tubes are intended for use in providing direct tracheal access for airway management.

NON-CLINIC DATA:

- ISO 5356-1: Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets. 2004.
- ISO 10993-1: Biological Evaluation of medical devices, part 1: Evaluation and testing, 2003.
- ISO 10993-5: Biological Evaluation of medical devices, part 5: Tests for in vitro cytotoxicity, 1999.
- ISO 10993-10: Biological Evaluation of medical devices, part 10: Tests for irritation and sensitization, 2002.

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- ISO 17665-1: Sterilization of health care products, part 1: validation and control of sterilization process for medical devices, 2006.

DEVICE DESCRIPTION:

The VITALTEC Rota-Trach Tracheostomy Tubes are made from the raw material of Silicone for medical use, with the component of connector and valve. The tracheostomy tubes have such good performances as the tube with appropriate hardness, the cuff with big capacity and low pressure, smooth tube and excellent biocompatibility.

COMPARISON WITH PREDICATE DEVICE:

ITEM	PREDICATE DEVICE	SUBJECT DEVICE
Name	Medical Tracheostomy Tubes (K031553)	VITALTEC Rota-Trach Tracheostomy Tubes
Intended Use	Tracheostomy Tubes are intended for use in providing direct tracheal access for airway management.	Same
Material	Silicone	Same
Connector	15 O.D. per ISO 5356-1	Same
Sterilization Method	ETO	Moist Heat
Specification	Various sizes for Pediatric and Adult	Pediatric I.D.: 5.0mm, 6.0mm Adult I.D.:7.0mm, 8.0mm, 9.0mm, 10.0mm
Cuff Style	Various types for Pediatric and Adult	Each one type of Air Cuff to match with each one size of Tracheostomy Tube

PERFORMANCE DATA

The dimension, design, material, sterility and packaging of VITALTEC Rota-Trach Tracheostomy Tubes are conformed to ISO 5356-1 and ISO 17665-1.

CONCLUSION

In accordance with the FDA 21 CFR 807 and based on the information provided in this premarket notification, VITALTEC Rota-Trach Tracheostomy Tubes have the same intended use, material, and use the same specification of connector which is complied with ISO 5356-1; and the different sterilization method was also got the validation. The main differences of the two devices are the subject device only has one type of air cuff and simpler specifications.

Thus the two devices are substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vitaltec Corporation
C/O Ms. Jen Ke-Min
Roc Chinese-European Industry Research Society
No. 58, Fu Chiun Street
Hsin Chu City
China (Taiwan) 30067

JUN 11 2010

Re: K100480
Trade/Device Name: Rota-Trach Tracheostomy Tube Model Rota-Trach
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: June 3, 2010
Received: June 10, 2010

Dear Ms. Ke-Min:

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.

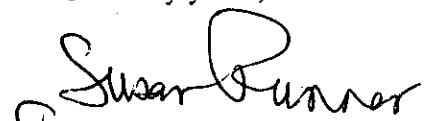
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510 (K) Number (If Known): K100480

- **Device Name:** *VITALTEC Rota-Trach Tracheostomy Tube*

Indications for Use :

Tracheostomy Tubes are intended for use in providing direct tracheal access for airway management.

⚠ *CAUTION: U.S. Federal law restricts the use of this device to licensed professionals.*

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100480