K120079

510(k) Summary

Primed® Tracheostomy Tubes MAY 2 4 2012

I. General information

- **Manufacturer**: Primed Halberstadt Medizintechnik GmbH
  Straße des 20. Juli 1
  38820 Halberstadt / Germany
- **Establishment Registration Number**: Must be applied for.
- **Contact Person**: Alexandra Singer
  Primed Halberstadt Medizintechnik GmbH
  Straße des 20. Juli 1
  38820 Halberstadt / Germany
  Phone: +49 3941 668 742
  Fax: +49 3941 245 65
  Email: alexandra.singer@primed-halberstadt.de

II. Device Identification

- **Proprietary/Trade Name**: *Primed Tracheostomy Tubes* (multiple)
- **Common/Usual Name**: Tracheostomy tube
- **Classification Name**: Tracheostomy Tube and Tube Cuff
- **Regulations Number**: 21 CFR 868.5800 together with
  - 21 CFR 868.5730 (Tube, Tracheal (W/Wo Connector)
  and
  - 21 CFR 868.5260 (Filter, Bacterial, Breathing-Circuit)
- **Regulatory Class**: Class II
- **Product Code**: BTO and JOH together with
  - BTR and
  - CAH
  (and also BYD (Class I; 868.5375) and KAC (Class I; 874.4420), which are both 510(k) exempt)
- **Device Panel**: Anesthesiology

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III. Predicate devices

There are several predicate devices marketed in the US with respect to the following characteristics: size, length, inner and outer diameter, materials including silver, with cuff and without cuff, speaking valve, Humid Moist Exchanger (HME) as well as a suction function. As an example the following predicate devices are mentioned here*:

- K051587 Tracoe-Vario Tracheostomy Tubes (various)
- K043160 Tracoe Phone Assist
- K961449 Tracheostomy Tubes Tracoe-flex
- K781729 Tracheostomy Tubes
- K083641 Bivona Tracheostomy Tube (silicone) by Smith Medical ASD
- K013321 Tracheal/Thoracic T-Tube by Technical Products, Inc.
- K063125 Filterflo HEPA by ARC Medical, Inc.

* Not mentioned here are the predicates, which are now 510(k) exempt.

IV. Description of device

The *Primed Tracheostomy Tubes* consists of various types of tracheostomy tubes, e.g., Primedistom Cannulas w/wo cuff, Silver Cannulas, Priflex Cannulas, Silicone Cannulas (Primedi Silk), and Primedi Star Cannulas. The tracheostomy tubes are made of different materials and offer a variety of inner and outer diameters and varying lengths thus making it possible to meet the individual needs of a patient.

The *Primed Tracheostomy Tubes* can be obtained sieved or unsieved, with or without speaking valve, cuffed or uncuffed, with or without one or two inner cannulas. The accessories comprise different speaking valves as well as Humid Moist Exchangers (HME) and different types of filters.

V. Indications of use

The *Primed Tracheostomy Tubes* are intended to provide tracheal access for airway management of tracheostomized patients.

VI. Technological characteristics

The *Primed Tracheostomy Tubes* do not have any sharp edges and are extremly user friendly. The adoption of the key features of the predicate devices was made intentionally in order to provide efficient and safe products. All *Primed Tracheostomy Tubes* are manufactured under clean room conditions and thereby fulfill high requirements with respect to cleanliness.

VII. Performance data

The *Primed Tracheostomy Tubes* conform to ISO 5356-1 and ISO 5366-1.

VIII. Conclusion

The *Primed Tracheostomy Tubes* have the same intended use as the predicate devices. They use the same materials and have the same specifications with respect to dimensions and functions. The minor changes made to the *Primed Tracheostomy Tubes* do not raise any new questions of safety and effectiveness.

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

Ms. Alexandra Singer
Regulatory Affairs
Primed Halberstadt Medizintechnik GmbH
Strasse Des 20. Juli Nr. 1
Halberstadt
GERMANY 38820

MAY 24 2012

Re: K120079
Trade/Device Name: Primed Tracheostomy Tubes (multiple)
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: May 8, 2012
Received: May 15, 2012

Dear Ms. Singer:

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,

for

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

Indications for Use

510(k) Number (*if known*): K120079

Device Name: *Primed Tracheostomy Tubes* (multiple)

Indications For Use:

The *Primed Tracheostomy Tubes* are intended to provide tracheal access for airway management of tracheostomized patients.

Prescription Use X 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: K120079