K123699

510(k) Summary

Fahl Tracheostomy Tubes

1 GENERAL INFORMATION

- **Manufacturer:** Andreas Fahl Medizintechnik-Vertrieb GmbH
  August-Horch-Str. 4a
  51149 Koeln / Germany
- **Establishment Registration Number:** 3007913402
- **Contact Person:** Claudia Winterschladen
  Regulatory Affairs Manager
  Andreas Fahl Medizintechnik-Vertrieb GmbH
  August-Horch-Str. 4a
  51149 Koeln / Germany
  Phone: +49 2203 2980-520
  Fax: +49 2203 2980-517
  Email: Winterschladen@fahl.de
- **Date summary was prepared:** August 12, 2013

2 DEVICE IDENTIFICATION

AUG 1 2 2013

- **Proprietary/Trade Name:** Fahl Tracheostomy Tubes:
  - Duravent,
  - Duracuff,
  - Laryngotec,
  - Duratwix,
  - Silvervent,
  - Spiraflex,
  - Tracheotec
- **Common/Usual Name:** Tracheostomy Tube
- **Classification Name:** Tracheostomy Tube and Tube Cuff
- **Regulations Number:** 21 CFR 868.5800 (Product Codes BTO and JOH) together with
  - 21 CFR 868.5730 (Tube, Tracheal (W/Wo Connector / BTR), and
  - 21 CFR 868.5375 (Condenser, Heat and Moisture (Artificial Nose); BYD; exempt)
- **Regulatory Class:** Class II
- **Product Code:** BTO together with
  - JOH
  - BTR
  - BYD (Class I; exempt)
- **Device Panel:** Anesthesiology

3 PREDICATE DEVICES

There are several predicate devices marketed in the US, which have the same intended use and similar design and technological characteristics. Substantially equivalence of the *Fahl Tracheostomy Tubes* is claimed to the following predicate devices:

- K120079 Primed Tracheostomy Tubes (Multiple) by Primed
- K961449 Tracoe Twist Tracheostomy Tubes by Tracoe
- K912124 Tracheostomy Tube and Cuff by Portex

4 DEVICE DESCRIPTION

The *Fahl Tracheostomy Tubes* (Duravent, Duracuff, Laryngotec, Duratwix, Silvervent, Spiraflex, and Tracheotec) are available cuffed or uncuffed. They can be obtained sieved or unsieved, with or without speaking valve, cuffed or uncuffed, with or without inner cannulas. The accessories comprise different Humid Moist Exchangers (HME), decannulation plugs, neck holders, and stoma buttons. *Fahl* offers the tubes in varying sizes and length so that the physician can select a tracheostomy tube, which best fits the individual needs of the patient. All *Fahl Tracheostomy Tubes* are for adults only and available on prescription.

5 INDICATIONS OF USE

The *Fahl Tracheostomy Tubes* are intended to provide tracheal access for airway management of tra-

cheostomized patients.

6 TECHNOLOGIC CHARACTERISTICS

The *Fahl Tracheostomy Tubes* (Duravent, Duracuff, Laryngotec, Duratwix, Silvervent, Spiraflex, and Tracheotec) equal the respective predicate devices in materials and sizes. The adoption of the key features of the predicate devices was made intentionally in order to provide efficient and safe products. All *Fahl Tracheostomy Tubes* are manufactured under clean room conditions and thereby fulfill high requirements with respect to cleanliness.

Duravent (with or without inner cannula), made of soft transparent polymer (radiolucent) with lateral x-ray contrast strip, sizes 3 to 13, different lengths, with 15 mm connector and/or 22 mm adapter.

Duracuff (with or without inner cannula) made of soft transparent polymer (radiolucent) with lateral x-ray contrast strip, sizes 7 to 12, different lengths, with 15 mm connector and/or 22 mm adapter, with a low-pressure cuff made of medical grade polymer.

Duratwix (with or without inner cannula), sizes 7 to 10, different lengths, with 15 mm swivel connector, with or without low-pressure cuff, pilot line of cuff is integrated into the outer cannula making the outer shape flush and smooth, available sieved or unsieved.

Silvervent (with inner cannula), made of seamless sterling silver, sizes 0 to 14, with or without 15 mm connector, default bent is 1/4 radius, conical tube (diameter of the tube decreases from neck flange to the cannula tip).

Spiraflex (with 1 inner cannula), with integrated metal spiral, which acts as X-ray contrast; sizes 7 to 11, with 15 mm connector; with an adjustable neck flange

Laryngotec (without inner cannula), made of soft and flexible silicone; size 7 to 13, with 22 mm adapter, neck flange tailored to the neck anatomy.

Tracheotec (without inner cannula), made from soft transparent medical-grade polymer, sizes 3 to 10, with 15 mm connector, with or without low-pressure cuff, pilot line is integrated into the outer cannula making the outer shape flush and smooth.

7 PERFORMANCE DATA

The *Fahl Tracheostomy Tubes* conform to applicable parts of the standards ISO 5356-1, ISO 5366-1, ISO 10993-1, and ISO 10993-7. Surface tension, tensile strength of wire-enforced tracheostomy tubes and attachment of the tubes to the neck flange were tested. Test results provide reasonable assurance that the tubes are safe for their intended use. The result and data of physical performance are given in the table below:

Requirement/ Tested Specification	Subject Device: Duravent	Subject Device: Laryngotec	Subject Device: Duracuff	Subject Device: Silvervent	Subject Device: Duratwix	Subject Device: Tracheotec	Subject Device: Spiraflex
Measurements of T. Tubes according to ISO 5366-1	Passed	Passed	Passed	Passed	Passed	Passed	Passed
Leak-Tightness of Tracheostomy tube with cuff according to ISO 5366-1	n.a.	n.a.	Passed	n.a.	Passed	passed	passed

Requirement/ Tested Specification	Subject Device: Duravent	Subject Device: Laryngotec	Subject Device: Duracuff	Subject Device: Silvervent	Subject Device: Duratwix	Subject Device: Tracheotec	Subject Device: Spiraflex
Diameter of air filled Cuff according to ISO 5366-1	n.a.	n.a.	Passed	n.a.	Passed	Passed	passed
Tensile Strength to the neck flange according 5366-1	Passed	n.a.	Passed	n.a.	Passed	Passed	passed
Tensile Strength of attachments of the tube to the neck flange 5366-1	Passed	n.a.	Passed	n.a.	Not tested	Passed	passed
Measurements of connectors According to ISO 5356-1	Passed	Passed	Passed	Passed	Passed	Passed	passed
Surface Strength of connectors according to ISO 5356-1	Passed	Passed	Passed	n.a.	Passed	Passed	passed
Leak-Tighteness of Connectors according to 5356-1	Passed	n.a.	Passed	n.a.	Passed	Passed	passed
Biocompatibility according to ISO 10993-1	Passed	Passed	Passed	n.a.	Passed	Passed	passed
Biocompatibility – Ethylene Oxide sterilization residuals according to ISO 100993-7	n.a.	passed	Passed	n.a.	passed	Passed	passed
Valdation of Sterilisation according to ISO 11135	passed	Not tested	Passed	n.a.	passed	passed	passed

8 SUBSTANTIAL EQUIVALENCE TABLE

Feature	Subject Device	Predicate	Subject Device	Predicate	Subject Device	Predicate
	Duravent	Primedistom K120079	Duracuff	Primedistom w cuff K120079	Silvervent	Primedi Silver K120079
Intended Use	Intended to provide tracheal access for airway management of tracheo-stomized patients.	Intended to provide tracheal access for airway management of tracheo-stomized patients.	Intended to provide tracheal access for airway management of tracheo-stomized patients.	Intended to provide tracheal access for airway management of tracheo-stomized patients.	Intended to provide tracheal access for airway management of tracheo-stomized patients.	Intended to provide tracheal access for airway management of tracheo-stomized patients.
Size range	3 to 13	3.5 to 13	7 to 12	8 to 11	0 to 14	0 to 14
Length (mm)	55 to 90*	55 to 90	65 to 90*	70 to 87	50 to 90	50 to 90
Bending angle	90°	90°	90°	90°	90°	90°
w/wo cuff	wo cuff	wo cuff	Low-pressure	Low-pressure	wo cuff	wo cuff

510(k) Summary

Fahl Tracheostomy Tubes

Feature	Subject Device	Predicate	Subject Device	Predicate	Subject Device	Predicate
Sterile packed	yes	yes	yes	yes	no	no
Material	Medical grade plastic	Medical grade plastic	Medical grade plastic	Medical grade plastic	Sterling silver	Sterling silver
Prescription use	yes	yes	yes	yes	yes	yes
Patient population	adult	adult	adult	adult	adult	adult
* These cannulas are also available in shorter and/or extra long.						

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Bending angle	90°	90°	90°	90°	90°	90°
w/wo cuff	wo cuff	wo cuff	Low-pressure	Low-pressure	wo cuff	wo cuff
Sterile packed	yes	yes	yes	yes	no	no
Material	Medical grade plastic	Medical grade plastic	Medical grade plastic	Medical grade plastic	Sterling silver	Sterling silver
Prescription use	yes	yes	yes	yes	yes	yes
Patient population	adult	adult	adult	adult	adult	adult
* These cannulas are also available in shorter and/or extra long.						

Feature	Subject Device	Predicate
	Tracheotec	Portex Blue line K912124
Intended Use	Intended to provide tracheal access for airway management of tracheo-stomized patients.	Intended to provide tracheal access for airway management of tracheo-stomized patients.
Size range	3 to 10	5 to 10
Length (mm)	47.2 to 105.3	Not available
Bending angle	95°	90°
w/wo cuff	w/wo low pressure cuff	w/wo low pressure cuff
Sterile packed	yes	yes
Material	Medical grade plastic	Medical grade plastic
Prescription use	yes	yes
Patient population	adult	adult

9 CONCLUSION

Fahl Tracheostomy Tubes have the same intended use as the predicate devices. The basic design elements and their assemblies are identical to the predicate devices. Variations in size or length do not impose a new risk on the devices as they conform to applicable parts of the ISO 5356-1, ISO 5366-1, ISO 10993-1, and ISO 10993-7. Determination of substantial equivalence of the *Fahl Tracheostomy Tubes* was based on a comparison of device intended use and materials of composition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 12, 2013

Andreas Fahl Medizintechnik-Vertrieb GmbH
Ms. Claudia Winterschladen
Regulatory Affairs Manager
August-Horch-Str. 4a
Koeln, Germany 51149

Re: K123699
Trade/Device Name: Fahl Tracheostomy Tubes (Multiple types: Duravent, Duracuff, Laryngotec, Duratwix, Silvervent, Spiraflex Tracheotec)
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH, BTO, BTR
Dated: May 29, 2013
Received: May 31, 2013

Dear Ms. Winterschladen:

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.

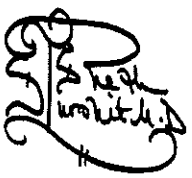
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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. 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,



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Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*): K123699

Device Name: *Fahl Tracheostomy Tubes* (Duravent, Duracuff, Laryngotec, Duratwix, Silvervent, Spiraflex, Tracheotec)

Indications For Use: *Fahl Tracheostomy Tubes* are intended to provide tracheal access for airway management of tracheostomized patients.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use __ (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)

Lester W. Schultheis Jr
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vision of Anesthesiology, General Hospital
ection Control, Dental Devices

510(k) Number: K123699