BEVER
Hangzhou Bever Medical Devices Co., Ltd.
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510(k) Summary K111401

JUL 19 2012

1. Submitter (Owner) of 510 (k):

Hangzhou Bever Medical Devices Co., Ltd.
No. 8-1, Longquan Rd., Cangqian Town, Yuhang District 311121, Hangzhou, China
Tel: +86-571-8861 6630 Fax: +86-0571-8861 6515
Registration Number: 3008729910

2. Contact person:

Allyson Zhou
Management Representative
Tel: +86-571-8861 6630 Fax: +86-0571-8861 6515
Email: zlshio1224@sina.com

3. Device Name:

Common Name: Endotracheal tube, Tracheal tube
Trade Name: BEVER™ Endotracheal tube and BEVER Eva™ Endotracheal tube
Classification name: Tracheal tube(W/Wo Connector) (21 CFR 868.5730, Product Code BTR)

4. Predicate Device:

BEVER is claiming substantial equivalence to the following medical devices:
Well lead Endotracheal tube - K042683
Hi-Lo Evac™ Endotracheal Tube - K965132

5. Device Description

BEVER™ Endotracheal Tube with cuff (Oral/Nasal) is available in sizes 3.0mm ~10.0 mm in 0.5 mm increments

BEVER™ Endotracheal Tube without cuff (Oral/Nasal) is available in sizes 2.0mm~9.0 mm in 0.5 mm increments

BEVER™ Endotracheal Tube with cuff (Oral preformed) is available in sizes 4.0mm~10.0mm in 0.5 mm increments

BEVER™ Endotracheal Tube without cuff (Oral preformed) is available in sizes 3.0mm ~9.0mm in 0.5 mm increments

BEVER™ Endotracheal Tube with cuff (Nasal preformed) is available in sizes 5.0mm ~10.0mm in 0.5 mm increments

BEVER™ Endotracheal Tube without cuff (Nasal preformed) is available in sizes 4.0 mm~9.0mm in 0.5 mm increments

BEVER Eva™ Endotracheal tube (Oral) is available in sizes 6.0mm~9.0mm in 0.5mm increments

The BEVER™ Endotracheal Tube made of polyvinyl chloride is sterile, single use device supplied with a standard 15 mm connector. The Endotracheal Tube is available in cuffed and uncuffed variants and is for oral or nasal use. The cuffed tube is composed of main tube, high volume/low pressure cuff, inflating system (including inflating tube, valve and pilot balloon) and 15mm connector. The uncuffed tube is composed of main tube and 15mm connector. The main tube incorporates a Magill curve, a beveled/hooded tip with Murphy eye and a tip-to-tip radiopaque line to assist in radiographic visualization.

The design of BEVER Eva™ Endotracheal tube is based upon the cuffed Endotracheal Tube (Oral/Nasal) with the addition of a third (integral) lumen within the tube. The lumen terminates above the cuff via a 'notch' (evacuation port) which enables the entrance (via suction) of secretions which have pooled above the cuff into the third (suction) lumen. Approximately half way along the tube length the suction lumen is joined to a suction tube which is external to the main tube. The suction tube is joined to the suction lumen in a similar manner to that of the joint between the inflating tube and the inflating lumen. The distal end of the suction tube terminates in a capped Luer connector which can be connected to either suction tubing or a syringe. The Eva™ Endotracheal tube is available in cuffed and for oral use.

6. Indications for Use

The BEVER™ Endotracheal tube is indicated for airway management by oral or nasal intubation of the trachea during mechanical ventilation and anesthesia.

The BEVER Eva™ Endotracheal tube is indicated for airway management by oral intubation of the trachea and for evacuation or drainage of the contaminated mucous and subglottic secretion that accumulate above the cuff by continuous or intermittent suctioning.

7. Substantial Equivalence

The BEVER™ Endotracheal tube and the BEVER Eva™ Endotracheal tube maintain the same intended use as the predicate devices. It is a device inserted into the trachea through the mouth or nose to facilitate breathing.

The BEVER™ Endotracheal tube and the BEVER Eva™ Endotracheal tube are composed essentially of the same materials as Well lead Endotracheal tube and Mallinckrodt Hi-Lo Evac™ Endotracheal Tube which has an additional suction lumen. The material for both devices is PVC.

The BEVER™ Endotracheal tube and the BEVER Eva™ Endotracheal tube have the same dimensions and design as the predicate devices - Well lead Endotracheal tube and Mallinckrodt Hi-Lo Evac™ Endotracheal Tube which has an additional suction lumen.

8. Device Performance

The dimension, design, material, sterility, packaging and labeling of BEVER™ Endotracheal tube and BEVER Eva™ Endotracheal tube are conformed with ISO 5361:1999(E) except for the suction lumen and suction tube of the BEVER Eva™ Endotracheal tube as described in clause 5.

9. Summary of Testing

Biocompatibility testing was performed based on ISO 10993-1: 2009. The subject device passed the following biocompatibility testings:

- Cytotoxicity
- Sensitization
- Irritation
- Genotoxicity
- Implantation

And the subject device is compliance with the following Biocompatibility standards:

- AAMI / ANSI / ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- AAMI / ANSI / ISO 10993-10: 2002/Amd. 1:2006(E) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1
- AAMI / ANSI / ISO 10993-6:2007 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- AAMI / ANSI / ISO 10993-3:2009 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

10. Sterility and shelf life

The device is sterilized by ethylene oxide. The sterilization process has been validated to be compliance with

- AAMI / ANSI / ISO ISO11135-1: 2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- AAMI / ANSI / ISO 10993-7: 2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Regarding the accelerated aging testing result, after 183 days accelerated aging, BEVER™ Endotracheal Tubes and BEVER Eva™ Endotracheal Tubes are still compliance the requirements of device specification. The shelf life of device could be considered as 4 years. And, according to the real time stability study, the 4 years shelf life of device has been validated. So the shelf life of subject device is 4 years.

11. Conclusions

These proposed devices have the same intended use and technological characteristics to the currently-marketed predicate devices. No new issues of safety or effectiveness are introduced by using these devices. Therefore we believe the proposed devices are substantially equivalent to the currently-marketed predicate devices.

12. Date of submission

January 13, 2012

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. Allyson Zhou
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No. 8-1, Longquan Road
Cangqian Town, Yuhang District
Hangzhou, Zhejiang
China 311121

JUL 19 2012

Re: K111401
Trade/Device Name: BEVER™ Endotracheal Tub and BEVER Eva Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: July 12, 2012
Received: July 12, 2012

Dear Ms. Zhou:

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):
Device Name: BEVER™ Endotracheal Tube and BEVER Eva™ Endotracheal Tube
Indications For Use:

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Prescription Use __Yes__ AND/OR Over-The-Counter Use __No__
(Part 21 CFR 801 Subpart D) (21 CFR 801 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: K111401