BEVER
Hangzhou Bever Medical Devices Co., Ltd.
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510(k) Summary K 111406

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
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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: Reinforced Endotracheal Tube, Reinforced Tracheal Tube
Trade Name: BEVER™ Reinforced 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 Reinforced Endotracheal Tube – K073383
Portex Reinforced Endotracheal Tube – K032112

5. Device Description

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

BEVER™ Reinforced Endotracheal Tube without cuff (Oral/Nasal) is available in sizes 2.0mm~7.0 mm in 0.5 mm increments

BEVER™ Reinforced Endotracheal tube is an Endotracheal tube with additional metal wire spiral reinforcement to provide kink-resistance. This type of product is typically used during operations where a high degree of flexibility is required from the tube, for instance prone position, head and neck surgery, and oral surgery. The plastic material and the spring allow the tube to be easily bent in all directions. The steel reinforcement maintains the patency of the lumen.

The BEVER™ Reinforced Endotracheal tube is sterile, single use device supplied with a standard 15 mm connector. It is available in cuffed and uncuffed variants and is for oral or nasal use. The cuffed tube is composed of main tube, cuff, inflating system (including inflating tube, valve and pilot balloon) and 15 mm connector. The uncuffed tube is composed of main tube and 15 mm connector. The cuff is intended to provide a seal against the trachea, ensuring that inspiratory and expiratory gasses are routed through the tube and not allowed to escape to the patient's upper airway, thus preventing loss of ventilation / anaesthetic and nebulised drugs, and reducing the likelihood of any aspirated stomach contents from entering the lungs. Uncuffed tubes are used mainly for paediatric patients or when patients require less protection from loss of ventilation / anaesthetic and nebulised drugs and or stomach aspiration.

6. Indications for Use

The BEVER™ Reinforced Endotracheal Tube is indicated for airway management by oral or nasal intubation of the trachea during anesthesia. The product may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

7. Substantial Equivalence

The BEVER™ Reinforced Endotracheal Tube maintains the same intended use as the predicate devices. It is a device inserted into the trachea through the mouth or nose to facilitate breathing and it may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

The BEVER™ Reinforced Endotracheal Tube is composed essentially of the same materials as the predicate devices. The material for both devices is PVC and stainless steel wire.

The BEVER™ Reinforced Endotracheal tube has the same design and performance characteristic as the predicate devices.

8. Device Performance

The dimension, design, material, sterility, packaging and labeling of BEVER™ Reinforced Endotracheal tubes are conformed with ISO 5361:1999 (E).

9. Summary of Testing

Biocompatibility testing was performed based on ISO 10993 standards. 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™ Reinforced 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
Management Representative
Hangzhou Bever Medical Devices Company, Limited
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Cangqian Town, Yuhang District
Hangzhou, Zhejiang
China 311121

JUL 19 2012

Re: K111406
Trade/Device Name: BEVER™ Reinforced 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™ Reinforced 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: K111406