K050803

JUN 3 0 2005

3.1 Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness
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Vitaid Ltd.
300 International Dr.
Suite 100
Williamsville, NY 14221

Tel: (716) 626-3428
Fax: (800) 655-5304

Official Contact: Will Stewart, President

Proprietary or Trade Name: Vitaid ET tubes

Common/Usual Name: Endotracheal tubes

Classification Name: Tracheal Tubes with and without connectors

Predicate Devices:
Unomedical – Standard ET Tubes K951696
Unomedical – Pediatric ET Tubes K951967
Sheridan – K822982 – Sheridan CF
Mallinckrodt – K852025 – Brandt Hi-contour

Device Description:

The Vitaid endotracheal tubes are available in sizes 3.0 mm to 10.0 mm in increments of 0.5 mm. They are available cuffed, uncuffed and with Murphy eye. Some are pre-formed, they are made with a ultra thin urethane cuff, referred to as the MicroCuff.

Indications:

Indications for Use -- The Vitaid ET Tubes are designed for oral / nasal intubation and are indicated for airway management. The Vitaid ET tubes have an ultra thin inflatable cuff.

Patient Population -- Patients requiring intubation

Environment of Use -- Institutional – Hospitals, Sub-acute
Pre-hospital – emergency services

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Comparison to Predicate Devices:

	Vitaid ET Tubes	Predicates
Attributes		
Indications for use	The Vitaid ET Tubes are designed for oral / nasal intubation and are indicated for airway management.	Unomedical – K951696 - Standard ET Tubes Unomedical – K951967 - Pediatric ET Tubes Sheridan – K822982 – Sheridan CF Mallinckrodt – K852025 – Brandt Hi-contour
Environments of use	Institutional - Hospital, Sub-acute Pre-hospital – emergency services	Same
Patient Population	Patients requiring intubation	Same
Contraindications	Use of endotracheal tubes in procedures which involve the use of laser beams or electrosurgical active electrodes in the immediate area of the device is contraindicated. Contact of the endotracheal tub with a laser beam or electrosurgical active electrode especially in the presence of oxygen-enriched mixtures could result in rapid combustion of the endotracheal tube with harmful thermal effects and with emission of corrosive and toxic products including hydrochloric acid (HCl).	Same
Technology		
Material	Tube – PVC Cuff – Polyurethane	Tube – PVC Cuff – PVC
Sizes – 3.0 mm to 10.0 mm	Yes	Yes
Cuffed and uncuffed, pre-formed with and without Murphy eye	Yes	Yes
Supplied Sterile	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

There are no significant differences between the proposed device, Vitaid ET Tubes, and the identified predicates.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Viataid, Ltd.
C/o Mr. Paul E. Dryden
ProMedic Incorporated
Regulatory Consultant for Vitaid Ltd.
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K050803
Trade/Device Name: Vitaid ET Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: II
Product Code: BTR
Dated: June 22, 2005
Received: June 23, 2005

Dear Mr. Dryden:

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.

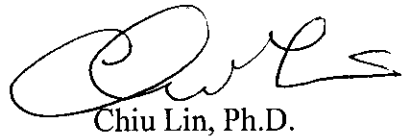
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.3 Indications for Use - Revised

510(k) Number: **K050803** (To be assigned)

Device Name: Vitaid ET Tubes

Indications for Use: The Vitaid ET Tubes are designed for oral / nasal intubation and are indicated for airway management. The Vitaid ET tubes have an ultra thin inflatable cuff.

Prescription Use XX or **Over-the-counter use** __
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K050803

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