K040657

510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Vygon, S.A.
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France
Telephone: (33) 1 39 92 63 63
Contact: Michel Hanania, Regulatory Affairs/Quality Assurance Manager
Date Prepared: March 11, 2004.

B. Device Name

Trade or Proprietary Name: *Boussignac/ Vygon Endotracheal Tube*

Common or Usual Name: Endotracheal Tube

Classification Name: Tracheal Tube

C. Predicate Devices

The subject device is substantially equivalent to the Mallickrodt *Hi-Lo® Jet Tracheal Tube* (K802505), and the Vygon's *Double Lumen Tracheal Tube* (K960795).

D. Device Description

The *Boussignac/ Vygon Endotracheal Tube* is a standard endotracheal tube available in varying diameters for both pediatric and adult use. The tube design includes a Magill curve, a tip, printed depth markings (in one centimeter increments), a low-pressure cuff (adult models only) and self-sealing valve with attached pilot balloon for cuff inflation/deflation. The tube also features a radiopaque line to assist in radiographic visualization. The device, including featured characteristics listed above, conforms to ISO 5361, *Anesthetic and Respiratory Equipment – Tracheal Tubes and Connectors*.

The tube has a main lumen and eight (8) separate canals, or "capillaries", embedded in the tube wall. In the adult model, five (5) of these canals are used for gas insufflation, two (2) for pressure control, CO_2 monitoring, or irrigation, and as in any endotracheal tube, one (1) canal is reserved for cuff inflation. In the *uncuffed* pediatric model, six (6) of the imbedded canals are used for gas insufflation, while two (2) are used for pressure control, CO_2 monitoring, or irrigation.

E. Intended Use

The *Boussignac/ Vygon Endotracheal Tube* is indicated for airway management. The insufflation canals permit the delivery of intermittent jet ventilation and the administration of oxygen during tracheobronchial suctioning procedures. They also provide a supplemental means for administering oxygen during bronchoscopies. In these ventilatory modes, the main lumen serves as a channel for the elimination of expired gases. When the insufflation port is capped, the *Boussignac/ Vygon Endotracheal Tube* can function as a standard tracheal tube with ventilation occurring through the main lumen. The *Boussignac/ Vygon Endotracheal Tube* is intended for oral/nasal intubation.

The monitoring/irrigation lumens may be used for monitoring airway pressure, for irrigation of a patient's tracheobronchial tree, to aid in the removal of accumulated secretions, for sampling tracheal gases, for anesthetizing the trachea, or for introducing suitable medication in accordance with standard medical practices.

F. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to its predicate devices, the Mallinckrodt *Hi-Lo® Jet Tracheal Tube* (K802505), and the Vygon's *Double Lumen Tracheal Tube* (K960795), cleared by the agency for commercial distribution in the United States.

The subject device has substantially equivalent indications for use as the Mallinckrodt *Hi-Lo® Jet Tracheal Tube*, being indicated for airway management via oral/nasal intubation.

The subject device is composed of the same materials as one or more of the predicate devices, all of which are established as safe for their application in the subject device.

The subject device encompasses design features which are substantially equivalent to those offered by the Mallinckrodt *Hi-Lo*® *Jet Tracheal Tube*, including a standard 15mm connector, a pilot balloon and valve for cuff inflation, low-pressure cuff adult models and uncuffed pediatric models, a radiopaque line and beveled tip, depth markings, a main lumen for the evacuation of expired gases and mucosal secretions, and insufflation lumen(s).

The subject device provides functions equivalent to those provided by the Mallinckrodt *Hi-Lo*® *Jet Tracheal Tube*, permitting the delivery of intermittent jet ventilation and the administration of oxygen during tracheobronchial suctioning procedures, providing a supplemental means for administering oxygen during bronchoscopies, and when the insufflation port is capped, both devices may also function as standard tracheal tubes with ventilation occurring through the main lumen. The monitoring/irrigation lumens may be used for monitoring airway pressure, for irrigation of a patient's tracheobronchial tree, to aid in the removal of accumulated secretions, for sampling tracheal gases, for anesthetizing the trachea, or for introducing suitable medication in accordance with standard medical practices.

Further, the subject device is packaged and labeled in a manner substantially equivalent to its predicate device, the Mallinckrodt *Hi-Lo*® *Jet Tracheal Tube*.

G. Summary of Non-Clinical Tests

Performance testing was presented.

H. Summary of Clinical Tests

Clinical publications were presented.

I. Conclusions of Non-Clinical and Clinical Tests

Performance testing and clinical publications were presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Ms. Laetitia Bernard
Excaelia, Inc.
45900 Parsippany Court
Temecula CA 92592

Re: K040657
Trade/Device Name: Boussignac Vygon Endotracheal Tube
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated on Submission: March 11, 2004
Date Received in ODE: March 12, 2004

Dear Ms. Bernard:

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 (301) 594-4646. 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/dsma/dsmamain.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

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K040657

Device Name: *Boussignac/ Vygon Endotracheal Tube*

Indications for Use:

The *Boussignac/ Vygon Endotracheal Tube* is indicated for airway management. The insufflation canals permit the delivery of intermittent jet ventilation and the administration of oxygen during tracheobronchial suctioning procedures. They also provide a supplemental means for administering oxygen during bronchoscopies. In these ventilatory modes, the main lumen serves as a channel for the elimination of expired gases. When the insufflation port is capped, the *Boussignac/ Vygon Endotracheal Tube* can function as a standard tracheal tube with ventilation occurring through the main lumen. The *Boussignac/ Vygon Endotracheal Tube* is intended for oral/nasal intubation.

The monitoring/irrigation lumens may be used for monitoring airway pressure, for irrigation of a patient's tracheobronchial tree, to aid in the removal of accumulated secretions, for sampling tracheal gases, for anesthetizing the trachea, or for introducing suitable medication in accordance with standard medical practice.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number: K040657