K031794

MAR 1 2 2004

Section E - 510(k) Summary

June 2, 2003

Applicant:
Merlyn Associates Inc.
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Irvine, CA 92620
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Email: jkotin.merlyn@cox.net

Application Preparer & Correspondent
Thomas E. Ferari
Medical Device Consultant
181 Dixon Road
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Proprietary Device Name: EndoFlex Tracheal Tube
Common Device Name: Endotracheal Tube
Classification Name: Tracheal Tube (Class II Device Ref 21CFR 868.5730)

Predicate Devices:
Cuffed Tracheal Tube K871204
Mallinckrodt Critical Care

Device Description: The EndoFlex Tracheal Tube is sterile, single use device for airway management during anesthesia and mechanical ventilation. The tube is made in fifteen sizes; 3.0mm through 10.0mm in 0.5 mm increments. The EndoFlex Tracheal tube is identical to the predicate devices in terms of material composition, biocompatibility, and sterilization. The EndoFlex Tracheal tube has a beveled tip, high volume/low pressure cuff, inflation system, and 15mm connector equivalent to the predicate devices. The EndoFlex Tracheal tube differs from the predicate device in the following ways:

- The EndoFlex Tracheal tube has an articulating tip that can be flexed to facilitate intubation. The flexing tip eliminates the need for intubation stylets.

Intended Use: The EndoFlex Tracheal Tube is intended for airway management by oral/nasal intubation.

Non-Clinical Performance Data: The EndoFlex Tracheal Tube was evaluated using the ASTM 1242-96 performance standard. The EndoFlex Tracheal Tube conforms to all of the performance standard criteria for materials, cuffs, inflation system, radius of curvature, marking

materials, and packaging. The tube passes all performance tests for tube collapse, cuff symmetry, cuff herniation, cuff pressure/volume/diameter assessment, radiopaque markers, and leak test.

Clinical Performance Data: To date, no clinical data has been collected.

Substantial Equivalence Assessment: Based on the non-clinical testing of the EndoFlex Tracheal Tube, it is equivalent to the predicate devices and both safe and effective for clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Merlyn Associates Incorporated
c/o Dr. Ching Ching Seah, Ph.D.
Amsino International, Incorporated
4501 Brickell Privado
Ontario, CA 91761

Re: K031794
Trade/Device Name: EndoFlex Tracheal Tube
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: January 8, 2004
Received: January 12, 2004

Dear Dr. Seah:

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.

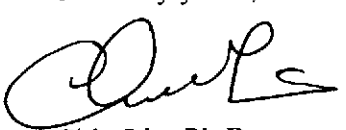
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Section D - Statement of Indications for Use

510(k) Number: K031794

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Proprietary Device Name: EndoFlex Tracheal Tube

Intended Use: The EndoFlex Tracheal Tube is intended for airway management by oral/nasal intubation.

✓ PRESCRIPTION USE

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K031794