K030787

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Nellcor

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510(k) Summary

Submitted by: Nellcor Puritan Bennett, Inc.
4280 Hacienda Drive
Pleasanton, CA 94588

Company Contact: Gina To
Senior Regulatory Affairs Project Manager
(925) 463-4427
(925) 463-4020 – FAX

Date Summary Prepared: June 24, 2003

Trade Name: Shiley® FlexTra™ Tracheostomy Tube

Common/Usual Name: Tracheostomy Tube

Classification Name: Tube Tracheostomy and Tube Cuff
JOH per 21CFR §868.5800

Substantially Equivalent Devices:

1. Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula, Mallinckrodt Inc., K003315
2. Shiley Tracheostomy Tubes and Accessories, Mallinckrodt Medical, K962173
3. Shiley Percutaneous Dual Cannula Tracheostomy Tube with Low Pressure / Lower Profile Cuff and Disposable Inner Cannula, Mallinckrodt Medical Inc., K963732
4. Modified Shiley Low Pressure Cuffed Tracheostomy Tube, Shiley Inc., K880247
5. Shiley Disposable Cannula Tracheostomy Tube with Low Pressure Cuff and Disposable Inner Cannula, Shiley Inc., K811447
6. Shiley Cuffed Single Cannula SCT Tracheostomy Tubes, Shiley Inc., K810106

DEVICE DESCRIPTION

The Shiley FlexTra disposable tracheostomy tubes are double cannula tracheostomy tubes with disposable inner cannula. The device is latex-free, sterile, and for single patient use only.

The device is intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The device is used to provide an artificial airway in order to assist in the treatment of a variety of respiratory diseases and airway management for adult patients. After insertion in place through a tracheotomy incision in the patient's neck and trachea, the device is then secured in place through the tracheostomy tube's swivel neck plate/flange with the use of a neck strap. Once in place, the device provides

a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Selected cuffed Shiley FlexTra products are also intended for use in conjunction with Percutaneous Dilatational Tracheotomy. The device is inserted into the patient using the appropriate loading dilator provided in a separate percutaneous dilatational kit. The device is intended to be used as an artificial airway immediately post tracheotomy.

INDICATIONS FOR USE

The Shiley FlexTra Tracheostomy Tube with Disposable Inner Cannula is intended to provide tracheal access for airway management.

Cuffed Shiley FlexTra products sizes 7.0, 8.0, and 9.0 mm ID are also intended for use with Percutaneous Dilatational Tracheotomy (PDT) procedures.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES

The Shiley FlexTra tracheostomy tube incorporates features and materials from the referenced Shiley predicate devices. The features that differentiate the Shiley FlexTra tracheostomy tube from the predicate devices include lengths, material of the inner cannula, and rigid tip on selected sizes of tracheostomy tubes designed to facilitate percutaneous dilatational tracheotomy insertion.

CONCLUSIONS

The technological characteristics of the Shiley FlexTra tracheostomy tube and the results of bench tests do not raise new questions of safety or effectiveness when compared to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Nellcor Puritan Bennett, Incorporation
Ms. Gina To
Regulatory Affairs Manager
4280 Hacienda Drive
Pleasanton, California 94588

Re: K030787
Trade/Device Name: Shiley Flextra Tracheostomy Tube
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: October 10, 2003
Received: October 14, 2003

Dear Ms. To:

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

510(k) Number (if known): K030787

Device Name: Shiley® FlexTra™ Tracheostomy Tube

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(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: K030787

Prescription Use ✓ OR Over-The-Counter Use ____

Optional Format (1-2-96)

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