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Healthcare

Nellcor

JUN 16 2005

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510(k) Summary

Submitted by:	Nellcor Puritan Bennett, Inc. 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	James Patrick Garvey II, RRT, RAC Regulatory Affairs Manager (925) 463-4479 - Phone (925) 463-4020 - FAX
Date Summary Prepared:	April 11, 2005
Product Name:	Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula
Common Name:	Tracheostomy Tube
Classification:	Class II; Tracheostomy tube and cuff 21 CFR §868.5800
Legally Marketed (Unmodified) Device:	• Mallinckrodt, Inc, K003315, Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula

DEVICE DESCRIPTION

The Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula includes an extended length outer cannula, extended length disposable inner cannula, tracheostomy tube holder, neck strap, and obturator. The device is used to provide an artificial airway, in order to provide access to the patient's airway for airway management. The device is introduced into a tracheotomy incision in the patient's neck that provides access to the trachea. The tracheostomy tube is secured by means of the swivel neck plate/flange that is connected to a tracheostomy tube holder or neck strap. When appropriately connected to a tracheostomy tube holder or neck strap, the device provides a secure artificial airway for spontaneous or mechanical ventilation.

INTENDED USE

- Purpose of The Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula is to provide tracheal access for airway management.
- The device is intended for use on adult patients.

INTENDED ENVIRONMENT OF USE:

- The device is intended for use in hospitals and hospital-type facilities, surgery centers, and home care environments.

- The device is contraindicated in procedures which will involve the use of LASER or an electrosurgical active electrode in the immediate area of the device. Contact of the beam or electrode with tracheostomy tube and inner cannula, especially in the present of oxygen-enriched or nitrous oxide containing mixtures could result in the rapid combustion of the tube with harmful thermal effects and with emission of corrosive and toxic combustion products including hydrochloric acid (HCl).

- The device is intended for sale by or on the order of a physician only.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the modified Shiley TracheoSoft Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula is the same as that for previously marketed Shiley TracheoSoft Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula. The materials and design of this device are similar to those of the predicate device. The technical characteristics of the device modification do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with The Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula provides similar information as the predicate devices.

Information provided in this Special 510(k) submission provides comparative, predicate device information and describes development procedures that support the determination of substantial equivalence and assertion that the modified device is safe and effective for its intended use. Product design and development, (including verification and validation testing, test and quality procedures) were conducted using internal company requirements, referencing external standards.

In summary, Nellcor Puritan Bennett has provided information that indicates the Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices, incorporating designs that have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2005

Mallinckrodt Medical
C/O Mr. Patrick Garvey
Nellcor Puritan Bennett Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

Re: K051416
Trade/Device Name: Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: May 31, 2005
Received: June 1, 2005

Dear Mr. Garvey:

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

510(k) Number (if known): _____

Device Name: Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula

Indications For Use:

The Mallinckrodt Inc. Shiley TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula are intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff is intended to establish a seal between the tracheal wall and the tracheostomy tube. This device is intended to be a component of a life-sustaining device to be used with adult patients.

Prescription Use: Yes (per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janette M. Michaud M.D.

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

510(k) Number: K051416