K971261

SEP 25 1997

510(k) Class II SUMMARY

Date Submitted: April 2, 1997

Submitter: Mallinckrodt Medical, Inc.
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Device Name: **Shiley Extended Length, Disposable Cannula, Tracheostomy Tubes**

Common Name and Classification: Tracheostomy Tube and tube cuff, 21 CFR 868.5800

Predicate Devices:

Predicate Device Names	Product Designations	510(k) Number
1. Smiths Industries Medical Systems (SIMS), Profile Tracheostomy Tubes with Portex Flexible Inner Cannulas.	"**100/528/xxx**" for 'Profile' Tracheostomy Tube with Flexible Inner Cannula "**100/522/xxx**" for Separate Flexible Inner Cannulas (sold separate from Tracheostomy tubes) ***(where "xxx" is the O/D size)***	Marketed in Europe since approx. 1992 (see product literature in **Appendix C**). No 510(k) filed in USA (Mallinckrodt owns the U.S. patent).
2. Specialized Tracheostomy Tubes	"**MODIFIED** xxx" (where xxx is the usual product designation of the modified tube)	K890194A, 7/20/89
3. Shiley Disposable Cannula, Low Pressure, Cuffed Tracheostomy Tube with *Soft Swivel Neck Flange feature.*	**DCT** and **DIC** (standard Disposable Inner Cannula included with DCT Tracheostomy Tube)	K962173, 10/4/96
4. Shiley Sleep Apnea Cuffed and Cuffless Tracheostomy Tubes	**SLP** (cuffed) **SCS** (cuffless)	K861463, 5/6/86 K861462, 5/6/86
5. Shiley Single Cannula Tracheostomy Tube	**SCT**	K810106, 2/2/81

Predicate Device Names	Product Designations	510(k) Number
6. Mallinckrodt Cuffed Tracheal Tube	**Hi-Lo® Tracheal Tubes**	K871204, 4/21/87
7. Mallinckrodt Critical Care Broncho-Cath Right Endobronchial Tube with CPAP Valve	**85815, 85816, 85817, and 85818**	K912230, 8/22/91

Device Description:

These devices are used to provide an artificial airway, in order to assist in the treatment of a variety of respiratory diseases and airway management in adults. After insertion in place through a tracheotomy incision in the patient's neck and trachea, the devices are then secured in place with a tiestrap around the patient's neck, which is attached to the tracheostomy tube's swivel neck plate/flange. Once in place, these devices provide a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Intended Use: The intended use of the modified devices will continue to be provision of tracheal access for airway management in adults.

Comparison of Technological Characteristics of Subject Versus Predicate Devices:

Similarities:

- The new devices will be available in extended lengths, up to 105mm (compared to the standard Shiley DCT). These lengths are comparable to the predicate Shiley Specialized Tracheostomy Tubes.
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- The new devices will be available in ***cuffed*** and ***uncuffed*** versions.
- Like predicate Shiley tracheostomy tubes, each Extended Length tracheostomy tube will be packaged with an obturator and neckstrap.
- Soft Swivel Neck Flange: This feature was found to be substantially equivalent to the current stiff swivel neck flange design in **510(k) #K962173** (cleared 10/4/96).
- The new devices' inflation cuffs will utilize the same material used in the Mallinckrodt Broncho-Cath Endobronchial Tube.

Differences:

- Non-arcuate tracheostomy tube shapes (compared to the arcuate standard Shiley DCT): The Extended Length Tracheostomy Tubes devices will vary in tube length along the **proximal** end of the tube (***before*** the curvature of the tube) **or** along the **distal** end of the tube (***after*** the curvature of the

tube), in order to accommodate unique anatomical needs. Comparable non-arcuate trach tube shapes are currently available in the predicate Shiley Specialized Trach Tubes and the Shiley Sleep Apnea Trach Tubes.

- *Flexible* extended length, disposable Inner Cannula. In order to accommodate the extended proximal and distal section lengths of these new devices, it was necessary to develop a more ***flexible*** Disposable Inner Cannula. The new ***flexible*** Extended Length Inner Cannula (**"XIC"**) has a "corrugated" appearance which allows the inner cannula increased lateral flexibility, while maintaining appropriate column strength. The predicate SIMS Profile device also features a flexible disposable Inner Cannula.

- The new XIC Disposable Inner Cannula terminates in an integral 15mm ***push***-lock Connector (current 15mm connectors on standard Disposable Inner Cannulae (DIC) feature an integral ***snap***-lock connector design).

- More flexible Outer Cannula body than the standard Shiley DCT (comparable to the predicate Mallinckrodt Hi-Lo Tracheal Tubes).

Performance/Clinical Data:

A. **In-vitro performance data:**

Test	Predicate Device Test Results	Modified Device Test Results	CEN Standard Requirements
Tie Strap Hole Strength:	26.7 lbs force (SCT)	45.8 lbs force	No requirement for this test parameter
Outer cannula body to Trach Head Base Bond Strength	143.0 lbs force (SCT)	55.0 lbs force	No requirement for this test parameter
Trach Head Base-to-Head Cap Bond	N/A	90.5 lbs force	No requirement for this test parameter
Cuff Burst Strength	8.3 lbs force (SCT)	6.6 lbs force	No requirement for this test parameter
15mm Connector Disconnect Force	19.1 lbs force (SCT)	19.4 lbs force	No requirement for this test parameter
Neck Plate to Trach Tube Body Attachment Strength:	42.1 lbs force (DCT)	27.7 lbs force	minimum 11.3 lbs force

B.. **Clinical Data:** Clinical data was not necessary, since device performance can be adequately assessed by in-vitro testing.

In conclusion, the similarities to the predicate devices, in conjunction with the physical integrity test results, demonstrate that the proposed modifications to these devices do not impact safety or effectiveness.

Summary:

The data presented demonstrate that the proposed modifications (extended proximal and distal lengths, flexible spiral inner cannula design) to Shiley Tracheostomy Tubes does not impact device performance characteristics and, thus, does not raise new safety and efficacy questions. This information supports the conclusion that the modified Shiley Tracheostomy Tubes and accessories are substantially equivalent in intended use, operation, and characteristics, as compared to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 25 1997

Mr. Michael B. Schoeck
Mallinckrodt Inc.
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P.O. Box 5840
St. Louis, Missouri 63134

Re: K971267
Shiley Extended Length, Disposable Cannula, Tracheostomy Tubes
(Models XCS-D, XCS-P, XLT-D, and XLT-P)
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: July 25, 1997
Received: July 28, 1997

Dear Mr. Schoeck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971267

Device Name: Shiley Extended Length, Disposable Cannula, Tracheostomy Tubes (Models XCS-D, XCS-P, XLT-D, and XLT-P)

Indications for Use:

To provide tracheal access for airway management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

(Optional Format 1-2-96)