K963732

SECTION 9; 510(k) SUMMARY OF SAFETY AND EFFICACY: (summary pg 1 of 3)

June 26, 1997

(1) Company Name Mallinckrodt Medical, Inc.

Address, Telephone and Contact

Corporate Headquarters	Manufacturing and Distribution Location
Mallinckrodt Medical, Inc. P.O. Box 5840 St. Louis, MO 63134	Mallinckrodt Medical, Inc. 18691 Jamboree Road Irvine, CA 92712
Mike Schoeck (314) 895-2318	Tony Wondka (714) 622-5797

Date of submission August 1996

(2) Trade Names Shiley Percutaneous Dual Cannula Tracheostomy Tube with Low Pressure / Lower Profile Cuff and Disposable Inner Cannula

Common or Usual Name Tracheostomy Tube, Adult, with Cuff

Classification Class II

(3) Substantially Equivalent Devices Registration numbers:

- Shiley DCT Dual Cannula Tracheostomy Tube with Low Pressure Cuff and Disposable Inner Cannula- 510(k) No. K811447.
- Shiley Cuffed Single Cannula SCT Tracheostomy Tubes - 510(k) No. K810106.

(4) Intended Use: 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. The device is intubated into the patient's neck and trachea through an opening that is created with dilators that are supplied in a separate Percutaneous Dilational Tracheotomy Kit. The intubation is performed by first inserting an Introducer, also supplied with the Kit, into the Trach Tube and second by passing the Introducer over a Guide Wire and finally through the dilated opening. The device is secured in place with sutures or by using a strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for ventilation or anesthesia equipment. The Cuff is intended to manage Tidal Volume leakage during Positive Pressure Ventilation and to assist in managing aspiration of food, fluids and secretions into the patient's lung.

(5) Description and Physical Characteristics: The device includes an Outer Cannula with a Cuff. The Cuff is deflated or inflated via an Inflation System comprised of tubing communicating between the Cuff and a Luer Valve to which a syringe can be attached. A Pilot Balloon is adjacent to the Luer Valve to indicate the inflation status of the Cuff. A Neck Plate is attached to the Outer Cannula. An Inner Cannula is included with an integral 15mm male conical connector. The Inner and Outer Cannula are attached together by a snap-lock mechanism. The Outer Cannula distal end is designed to have smooth transitions in outer diameter in order to minimize the amount of resistance that would occur with abrupt transitions.

(6) Materials: The device consists of an Outer Cannula, Cuff, Inflation Line, Pilot Balloon, Luer Valve and Inner Cannula all constructed with biocompatible polyvinyl chloride, an obturator and 15mm male connector both constructed with biocompatible polypropylene, and a neck plate constructed with biocompatible polycarbonate.

(7) Differences from Predicate Devices referenced herein:

The device is not different in safety or efficacy from the predicate device(s). The design differences between the new PERC device and the Shiley 'DCT' predicate device are related to a relatively smooth tip for the PERC compared to the DCT.

Similarities to DCT and SCT devices:

1) Dual Cannula System (same as DCT)
2) Inner Cannula in its entirety (same as DCT)
3) Outer Cannula length (same as DCT)
4) Outer Cannula ID and OD (same as DCT)
5) Cuff and Inflation System components (same as DCT)
6) Cuff attachment to Outer Cannula (same as DCT and SCT)
7) Inflation Line attachment to Outer Cannula (same as DCT)
8) Intended Use of device (same as DCT)
9) Sterilization Method (same as DCT and SCT)

Differences from DCT device:

Physical Characteristics:

1) The Outer Cannula includes a distal tip section that has smooth gradual transitions in diameter. This is accomplished by eliminating the lip caused by the rim of the distal cuff bond. In addition, the proximal Cuff bond is inverted to reduce the effective diameter of this section of the device. These characteristics are intended reduce the amount of force necessary to insert the device into the patient.

Labeling and User Instructions:

1) The device instruction sheet will include references to Cuff Resting Diameter, Cannula Angle, and Proximal and Distal Extensions as suggested in the ISO and CEN standards.

2) A statement will be added to the packaging indicating that the new device is compatible with Introducers provided with Percutaneous Dilational Tracheotomy Kits.

3) A Caution statement indicating that physicians using this device with a Percutaneous Dilational Tracheotomy Procedure should be properly instructed on the procedure prior to use.

4) A Caution statement indicating that prior to intubation of this device, that the preceding Percutaneous Dilational Tracheotomy Procedure be performed with visual confirmation of needle and/or guide catheter placement from inside the trachea with a bronchoscope or similar manner.

5) A statement will be added that states sterile technique should be used when inserting the device into the patient since the intubation will be performed in conjunction with a Percutaneous Dilational Tracheotomy Procedure.

6) A statement will be added to describe a method of deflating the device prior to removal from the patient to taper the cuff in the direction of removal.

(8) Test Summary:

1) Non-Clinical Tests:

Physical integrity of the Cuff-to-Cannula bond strength of the new PERC device will be demonstrated to be equivalent to the predicate DCT device.

Insertion force of the new PERC device will be less than that of the predicate DCT device.

This data will be available from the manufacturer upon request.

2) Clinical Tests:

It is not required to conduct clinical tests on the new PERC product due to its similarity to the predicate DCT product and other competitor's predicate products. Moreover, we estimate that approximately 4000 DCTs are currently used in this application annually. The acceptance of the predicate DCT in this application eliminates the need to validate the acceptance of the new PERC product in this application because of the minor nature of the improvements.

3) Conclusion:

The similarity to the predicate products in conjunction together with the extensive usage of the predicate product in Percutaneous Dilational Tracheotomy applications, demonstrate that the new PERC product is safe and effective and will perform equal to or better than currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1997

Mr. James E. Keller
Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, Missouri 63134

Re: K963732
Percutaneous Dual Cannula Tracheostomy Tube with Low Pressure/Low Profile Cuff and Disposable Inner Cannula
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: May 8, 1997
Received: May 12, 1997

Dear Mr. Keller:

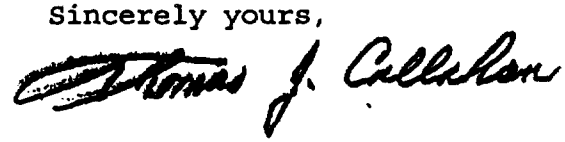
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K963732

Device Name: Percutaneous Dual Cannula Tracheostomy Tube

Indications For Use:

1. This 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.
2. The device is to be used by the order of a physician.
3. The device is primarily intended for use in conjunction with Percutaneous Dilational (or Dilatational) Tracheotomy and is inserted into the patient using the Introducer provided with the Percutaneous Dilational Kit.
4. The device is intended to be used as the initial artificial airway immediately post tracheotomy.
5. There is no "new" intended therapeutic use of this device to existing devices marketed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Bozeval for RNP

(Division Sign-Off)
Division of Cardiovascular, [redacted],
and Neurological Devices
510(k) Number K963732

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

(Optional Format 1-2-96)