Exhibit #7

JUL 31 1996 K961977

510(k) Summary

Kendall SHER-I-BRONCH® Endobronchial Tube

In accordance with section 513(i) the SMDA and as described in 21 CFR Part 807.3, final rule dated December 14, 1994, this summary is submitted by:

Kendall Healthcare Products Company
15 Hampshire Street
Mansfield, MA 02048
Date: March 20, 1996

1. Contact Person

David A. Olson
Manager Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

| | |
|---|---|
| Classification Name | Tracheal/Bronchial Differential Ventilation Tube |
| Common or Usual Name: | Tracheal Tube |
| Proprietary Name: | SHER-I-BRONCH® Endobronchial Tube |

3. Identification of Legally Marketed Device

The proposed Kendall SHER-I-BRONCH® Endobronchial Tube is substantially equivalent in intended use function and composition to the commercially available Kendall SHER-I-BRONCH® Endobronchial Tube (510(k) No. K851856) and Mallinkrodt Broncho-Cath® Endobronchial Tube (510(k) No. K771219).

4. Device Description

The proposed Kendall SHER-I-BRONCH® Endobronchial Tube is a sterile, single use device which is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung. SHER-I-BRONCH® is available in 28 Fr, 35 Fr, 37 Fr, 39 Fr and 41 Fr sizes. The tube design incorporates a dual lumen configuration with labeled bronchial and tracheal lumens. The bronchial cuff and corresponding pilot balloon are blue in color, while the tracheal cuff and

its pilot balloon are white. Included as sterile items with the SHER-I-BRONCH® are three suction catheters, two 15 mm double swivel airway connectors, one "Y" adapter and one stylet.

5. Device Intended Use

The Kendall SHER-I-BRONCH® Endobronchial Tube is intended for use in thoracic surgery, bronchospirometry, for the administration of endobronchial anesthesia and other uses commonly requiring endobronchial intubation. The tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.

6. Product Comparison

The Kendall SHER-I-BRONCH® Endobronchial Tube is equivalent to the referenced predicate device in that they are fabricated from identical materials, have the same function and equivalent indications for use.

7. Nonclinical Testing

Biocompatibility testing was performed on the endobronchial tube following ISO-10993 Biological Evaluation of Medical Devices. This testing found the material contained no toxic diffusible substances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David A. Olson
Kendall Healthcare Products Company
15 Hampshire Street
Mansfield, Massachusetts 02048

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Re: K961977
Kendall SHER-I-BROCH® Endobronchial Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tube, tracheal/bronchial, differential ventilation (w/wo connector)
Regulatory Class: Two (II)
Product Code: 73 CBI
Dated: May 16, 1996
Received: May 20, 1996

Dear Mr. Olson:

This letter corrects our substantially equivalent letter of July 31, 1996.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Division 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: Kendall SHER-I-BRONCH® Endobronchial Tube

Indications For Use:

The endobronchial tube is intended for use in thoracic surgery, bronchospirometry, administration of endobronchial anesthesia and other uses commonly requiring endobronchial intubation. The tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hung Truh for TC

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K961977

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

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