# 510 (k) SUMMARY

**Submitted By:**
Masahiko Nishimoto
Director, Product Quality Center
Daiken Medical Co., Ltd.
2-6-2 Ayumino, Izumi-city
Osaka, Japan 594-1157

MAR 2 0 2008

**Device:**

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| Trade Name: | Coopdech Endobronchial Blocker Tube |
| Common Name: | Tracheal/bronchial differential ventilation tube (w/wo connector) |
| Classification Name: | Tube, Tracheal/bronchial, differential ventilation (w/wo connector) |

**Predicate Device or Legally Marketed Devices:**
Cook "7.0 Fr. Endobronchial Blocker" (k021920)
Cook "Tip Deflecting Endobronchial Blocker" (k013865)

**Device Description:**
The "Coopdech Endobronchial Blocker Tube" consists of a bronchial blocker tube; advanced through an endotracheal catheter, and a joint connector, connecting the bronchial blocker tube to the endotracheal catheter. A cuff, incorporated at the distal tip of the tube, is inflated to block the targeted bronchus.
The "Coopdech Endobronchial Blocker Tube" is intended for use to differentially intubate a patient's bronchus in order to isolate the right or left lung for procedures which require one-lung ventilation.

**Indications for Use:**

The COOPDECH Endobronchial Blocker Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Patient Population: Patients requiring one lung isolation.

Environment of Use: Hospitals-OR and ICU.

**Substantial Equivalence:**
The "Coopdech Endobronchial Blocker Tube" has the same intended use as the Cook "7.0 Fr. Endobronchial Blocker" (k021920) and the Cook "Tip Deflecting Endobronchial Blocker" (k013865). The "Coopdech Endobronchial Blocker Tube" has similar materials and design features as the Cook "7.0 Fr. Endobronchial Blocker" (k021920). Testing elements to verify the design of the Coopdech Endobronchial Blocker Tube are the same as the Cook "Tip Deflecting Endobronchial Blocker" (k013865) indicating the same design features between the two products. The gas barrier property of the "Coopdech Endobronchial Blocker Tube" is at least equal to the Cook "7.0 Fr. Endobronchial Blocker" (k021920).

Since the "Coopdech Endobronchial Blocker Tube" contains equivalent specifications, features and performance characteristics compared to both the Cook "7.0 Fr. Endobronchial Blocker" (k021920) and the Cook "Tip Deflecting Endobronchial Blocker" (k013865), DAIKEN ascertained that the "Coopdech Endobronchial Blocker Tube" is substantially equivalent to the above two (2) referenced devices.

**Test Data:**
The Coopdech Endobronchial Blocker Tube was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests included:

- Analysis of Bond Strength
- Analysis of Deflection Angles
- Analysis of Cuff Pressure and Dimension at Various Inflation Volumes
- Balloon Burst Testing
- Analysis of Balloon Cuff Inflation Retension (internal specification)
- Evaluation of Balloon to Shaft Bond
- The dimension and the ports of the joint connector
- Endotoxin tests
- Biocompatibility tests

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for use as a Bronchial Differential Ventilation Tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2008

Daiken Medical Company, Limited
C/O Fumiaki Kanai, Ph.D.
President and Chief Executive Officer
MIC International
4-2-1 Yushima, Bunkyou-ku
Tokyo 113-0034
JAPAN

Re: K071694
Trade/Device Name: Coopdech Endobronchial Blocker Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: February 19, 2008
Received: February 21, 2008

Dear Dr. Kanai:

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) 276-0115. 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

# Indications for Use

510(k) Number (If known): 071694

Device Name: Coopdech Endobronchial Blocker Tube

Indications for Use:

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Patient Population: Patients requiring one lung isolation.

Environment of Use: Hospitals-OR and ICU.

Prescription Use X AND/OR Over-the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



510(k) Number: K071694