K093888

Section 5- 510(k) Summary

MAR 1 6 2010

a. Owner/Company name, address

DAIKEN MEDICAL CO., LTD.
2-6-2 Ayumino, Izumi-city,
Osaka, 594-1157, Japan

Seiji Nakagawa
Director, R&D Center
Phone: 011-81-725-51-3525
Fax: 011-81-725-54-0425

b. Contact/Application Correspondent

Fumiaki Kanai, Ph.D.
President and CEO
MIC International (4th Floor)
4-1-17 Hongo, Bunkyo-ku
Tokyo, 113-0033, Japan

Phone: 011-81-3-3818-8577
Fax: 011-81-3-3818-8573
Email: kanaif@mici.co.jp

c. Date prepared

November 17, 2009

d. Name of device

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)
Classification Regulation:	21 CFR 880.5740

e. Predicate devices

The COOPDECH ENDOBRONCHIAL BLOCKER TUBE is substantially equivalent to the following legally marketed devices:

The same trade name with the device for the application;

510(k):	k071694
Trade name:	COOPDECH ENDOBRONCHIAL BLOCKER TUBE
Product code:	CBI

Because the same device name as the predicate device is used, we call the device under the application, as "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" in this premarket notification application.

f. Description of the device

The "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" 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 (MODIFIED)" is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

g. Indications for Use

Indication 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.

h. Statement of substantial equivalence

The characteristics of the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" are similar to those of the predicate devices described in Item e above. The similarities include:

- Same Intended Use
- Same operating principals
- Same design features
- Ethylene Oxide Sterilized
- Single Sterile Wrapped
- Multiple Length

The materials of the cuff, the sheath, the mark and the O-ring in the joint connector from the predicate device are changed in the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)".

In order to evaluate the above changes, the biocompatibility tests (Section 16), the performance tests –bench (Section 19) and the shelf-life tests (Section 15) were performed. Those tests indicated that the above changes did not raise concern in its safety and performance.

Because there is no other changes in "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" other than the above mentioned material changes, the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)"contains almost equivalent specifications, features and performance characteristics compared to the predicate device, DAIKEN concluded that the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" is substantially equivalent to the predicate device.

Table 1. Comparison Table

Items	Predicate Device	"COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)"
Intended 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.	Same
Materials	Nylon, Silicone, PP, Nitrile rubber	Nylon, Silicone, PP, Isoprene rubber, Polyurethane
Design features	Double lumen shaft, multi-port adaptor, 2 cuffs,	Same
Tests for verifying characteristics of the cuff	● Analysis of Cuff Pressure at Various Inflation Volumes ● Balloon Burst Testing ● Analysis of Balloon Cuff Inflation Retention	Same
Gas barrier property	Gas barrier property was tested by analyzing the balloon cuff inflation retention time as shown in the bench test.	Same
Length	30, 40, 50, 60, 70, 80 cm	Same
Sterilization Method	EtO Sterilized	Same

i. Bench Testing

Because of the material changes in the Cuff, we performed following tests in order to evaluate the material change.

- Analysis of Cuff Pressure at Various Inflation Volumes
- Balloon Burst Testing
- Analysis of Balloon Cuff Inflation Retention

We have obtained almost the same results in the above three tests, and thus those results demonstrated that the characteristics of "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" are substantially equivalent to the predicate device. The test results are included in Section 19 Performance testing- Bench.

j. Biocompatibility testing

As mentioned in the above Item h, there are material changes in several parts including

the cuff, the sheath and the mark which directly contact mucosa. Therefore, biocompatibility tests were performed to evaluate the material changes.
As same as the predicate device, no biocompatibility concern was raised in such biocompatibility tests of the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)", which showed substantial equivalence regarding biocompatibility between the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" and the predicate device. The test results are included in Section 16 Biocompatibility.

k. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to the predicate device, DAIKEN MEDICAL CO., LTD concludes that the "COOPDECH ENDOBRONCHIAL BLOCKER TUBE (MODIFIED)" is substantially equivalent to the predicate device.

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

Daiken Medical Company, Limited
C/O Dr. Fumiaki Kanai
President and Chief Executive Official
MIC International
4-1-17 Hongo, Bunkyo-Ku
Tokyo, 113-0033, Japan

MAR 1 6 2010

Re: K093888
Trade/Device Name: Coopdech Endobronchial Blocker Tube
Regulation Number: 21CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: November 17, 2009
Received: December 18, 2009

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

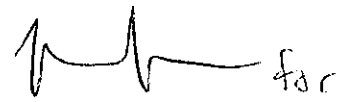
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.
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): K093888

Device Name: COOPDECH ENDOBRONCHIAL BLOCKER TUBE

Indication 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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

510(k) Number: K093888