

K071365

510(k) SUMMARY

Bard Medical Division, C.R. Bard, Inc.'s Agento™ I.C.® Silver-coated Endotracheal Tube

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Bard Medical Division, C.R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014

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Contact Person: Michelle R. Gudith, Director, Regulatory Affairs

Date Prepared: March 30, 2007

Name of Device and Name/Address of Sponsor

Agento™ I.C.® silver-coated endotracheal tube

Bard Medical Division, C.R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014

NOV 06 2007

Common or Usual Name

Endotracheal tube

Classification Name

Tube, Tracheal (W/WO Connector)

Predicate Devices

Mallinckrodt Hi-Lo® / Intermediate Hi-Lo Cuffed Tracheal Tubes

Intended Use / Indications for Use

Agento™ I.C.® silver-coated endotracheal tube is indicated for airway management by oral or nasal intubation of the trachea for anesthesia and in cases where duration of intubation is expected to be 24 hours or longer, or may be unpredictable.

Agento™ I.C.® silver-coated endotracheal tube has been shown to reduce the incidence of microbiologically confirmed Ventilator Associated Pneumonia (VAP) in patients intubated for 24 hours or longer from an incidence of 7.5% in patients intubated with uncoated ET tubes to an incidence of 4.8% in patients intubated with the Bard Silver-Coated ET tubes (reduction of 36%) and to delay the time to onset of microbiologically confirmed VAP.

For Adults Only

Technological Characteristics

Agento™ I.C.® silver-coated endotracheal tube is a sterile bifurcated (two-lumen) polyvinyl chloride tube with a polyvinyl chloride cuff. The tube design incorporates a Magill curve and features a radiopaque line to assist radiographic visualization. An indicator (ORAL: NASAL) is provided on standard length tubes to mark the tracheal tube length in centimeters. This indicator and all other device features listed above were tested in accordance with the American Society for Testing and Materials (“ASTM”) designation F 1242-96, Standard Specification for Cuffed and Uncuffed Tracheal Tubes. The Bard Silver-coated Endotracheal Tube is available with a hooded Murphy tip, a high volume, low pressure cuff and self-sealing valve with attached pilot balloon. The Bard Silver-coated Endotracheal Tube is available in sizes of 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, and 10.0 mm ID.

Agento™ I.C.® silver-coated endotracheal tube is coated on the outer endotracheal tube surface, including the cuff surface, and on the interior surface of the airway lumen with a proprietary hydrophilic silver coating. Neither the inside of the cuff nor the inside of the inflation lumen is coated.

Performance Data

In vitro microbial assays, functional performance testing, biocompatibility testing, and animal studies have demonstrated the safety and effectiveness of the Agento™ I.C.® silver-coated endotracheal tube. Clinical studies of the Agento™ I.C.® silver-coated endotracheal tube demonstrated a reduction in the incidence and time to onset of VAP compared to the predicate uncoated endotracheal tube.

Substantial Equivalence

Agento™ I.C.® silver-coated endotracheal tube is as safe and effective as the Mallinckrodt Hi-Lo® / Intermediate Hi-Lo Cuffed Tracheal Tubes. The Agento™ I.C.® silver-coated endotracheal tube has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The technological differences between the Agento™ I.C.® silver-coated endotracheal tube and its predicate device raise no new issues of safety or effectiveness. In vitro, bench, animal and clinical data demonstrate that the Agento™ I.C.® silver-coated endotracheal tube is as safe and effective as the Mallinckrodt Hi-Lo® / Intermediate Hi-Lo Cuffed Tracheal Tubes. Thus, the Agento™ I.C.® silver-coated endotracheal tube is substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 06 2007

Ms. Michelle R. Gudith
Director of Regulatory Affairs
C.R. Bard, Incorporated
Bard Medical Division
8195 Industrial Boulevard
Covington, Georgia 30014

Re: K071365
Trade/Device Name: Agento™ I.C.® Silver-Coated Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: September 28, 2007
Received: October 1, 2007

Dear Ms. Gudith:

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 Statement

510(k) Number (if known): K 071365

Device Name: Agento™ I.C.® Silver-coated Endotracheal Tube

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For Adults Only

Prescription Use <u> X </u>	AND/OR	Over-The-Counter
Use <u> </u>		
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 807
Subpart C)		

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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