K080170

Attachment 4

MAR 25 2008

510(k) Summary

Product	Agento™ I.C.® Silver-Coated Endotracheal Tube (Intermediate High Volume Low Pressure)
Submitter's Information	Skip Rimer Regulatory Affairs Specialist II Bard Medical Division C.R. Bard Inc. 8195 Industrial Blvd. Covington, Georgia 30014 USA Phone (770) 784-6160, Fax (770) 784-6419 E-mail skip.rimer@crbard.com
Date Prepared	January 21, 2008
Name of Device	Agento™ I.C.® Silver-Coated Endotracheal Tube (Intermediate High Volume Low Pressure)
Name/Address of Sponsor	C.R. Bard Inc. Bard Medical Division 8195 Industrial Blvd. Covington, Georgia 30014 USA Phone (770) 784-6722, Fax (770) 385-4768
Common or usual names	Endotracheal tube
Classification name	Tube, Tracheal (W/Wo Connector)
Predicate devices	K071365, Agento™ I.C.® Silver-Coated Endotracheal Tube
Intended use and indications for use	Intended Use The Agento™ I.C.® Silver-Coated Endotracheal Tube intended use is 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

The Bard 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 International Organization for Standardization (ISO) 5361, Anesthetic and Respiratory Equipment – Tracheal Tubes and Connectors. The Bard Silver-coated Endotracheal Tube is available with a hooded Murphy tip, a intermediate 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.

The Bard 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

Functional, biocompatibility and predicate device comparative testing have demonstrated that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2008

Mr. Skip Rimer
Regulatory Affairs Specialist II
C.R. Bard, Incorporated
8195 Industrial Boulevard
Covington, Georgia 30014

Re: K080170
Trade/Device Name: Agento™ I.C.® Silver-Coated Intermediate High Volume Low Pressure Endotracheal (ET)Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: March 6, 2008
Received: March 10, 2008

Dear Mr. Rimer:

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.

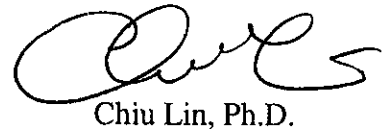
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K080170

Device Name: Agento™ I.C.® silver-coated intermediate high volume low pressure endotracheal (ET) tube

Indications for Use:

The Agento™ I.C.® silver-coated intermediate high volume low pressure endotracheal (ET) 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.

The Agento™ I.C.® silver-coated intermediate high volume low pressure endotracheal (ET) 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

Prescription Use __X___ AND/OR Over-The-Counter Use____
(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)

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

510(k) Number: 3/24/08