K030792

NOV 14 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name:	C. R. Bard, Inc., Medical Division
Address:	8195 Industrial Blvd. Covington, Georgia 30014
Contact Person:	Frances E. Harrison, RAC
Contact Person's Phone:	(770) 784-6257
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	August 28, 2003

B. Device Name:

Trade Name:	Bard® Endotracheal Tube, Cuffed
Common / Usual Name:	ET Tube
Classification Name:	Tracheal Tube

C. Predicate Device Name:

Mallinckrodt Hi-Lo®/Intermediate Hi-Lo Tracheal Tube, Cuffed

Trade Name: Same as above.

D. Device Description: The Bard® Endotracheal Tube, Cuffed is a single lumen tube with a cuff. The lumen is used for airway management/gas transport and is connected to a ventilator via a connector. The two-way valve on the cuff inflation tube is assembled to a pilot inflation line/pilot balloon assembly that is bonded to the tube to lead into the inflation lumen. The Bard Endotracheal Tube is offered in the following sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, and 10.0mm.

E. Intended Use: The Bard® Endotracheal Tube, Cuffed is indicated for airway management by oral/nasal intubation of the trachea for anesthesia.

F. Technological Characteristics Summary: The Bard® Endotracheal Tube, Cuffed is constructed of polyvinyl chloride. It has the same intended use and design and is manufactured from the same biocompatible materials and offered in the same sizes as the predicate device.

G. Performance Data Summary: The Bard® Endotracheal Tube, Cuffed is constructed of biocompatible materials and has been tested using ASTM F 1242-96, "Standard Specification for Cuffed and Uncuffed Tracheal Tubes". Both the Bard device and the predicate device meet the ASTM standard with the exceptions of radius of curvature and device markings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Ms. Frances E. Harrison, RAC
Director, Regulatory Affairs
C.R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014

Re K030792
Trade/Device Name: Bard Endotracheal Tube, Cuffed
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: August 15, 2003
Received: August 20, 2003

Dear Ms. Harrison:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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): K030792

Device Name: Bard® Endotracheal Tube

Indications for Use:

The Bard Endotracheal Tube, Cuffed is indicated for airway management by oral/nasal intubation of the trachea for anesthesia

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

(Optional Format 1/2/96)

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

510(k) Number: K030792