JAN 1 4 2004

K033936
Page 1 of 2

BARD ENDOSCOPIC TECHNOLOGIES
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

BARD

VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

Submitter's Name:	Bard Endoscopic Technologies C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3 Billerica, MA 01821
Phone:	(978) 262 – 4868
Fax:	(978) 262 – 4878
Contact Person:	Michael A. Patz
Date of Preparation:	December 18, 2003

B. Device Name

Trade Name:	Bard® ELIMINATOR® PET Balloon Dilators
Common/Usual Name:	Dilator, Esophageal, Biliary
Classification Name:	Biliary Catheter/Accessories, Esophageal Dilator

C. Predicate Device Name(s)

Trade Name:	Bard® ELIMINATOR® PET Balloon Dilators

D. Device Description:

The Bard® ELIMINATOR® PET Balloon Dilators are comprised of a radioopaque polyurethane catheter with an internally fixed guide wire and a high-pressure non-distending PET balloon.

E. Intended Use:

The Bard® ELIMINATOR® PET Balloon Dilators are used to dilate strictures of the GI tract including the colon, pylorus and esophagus.

F. Technological Characteristics Summary:

The modified Bard® ELIMINATOR® PET Balloon Dilators is comprised of the same medical grade plastics, stainless steels and balloon material as the current device.

G. Performance Data:

Biocompatibility testing was not conducted for this product line extension, as there were no material changes. The only design change was the addition of a 20 mm balloon dilator size. Functionality testing, Failure Pressure and Inflation/Deflation testing were completed and demonstrated that the modified Bard® ELIMINATOR® PET Balloon Dilators are substantially equivalent to the current Bard® ELIMINATOR® PET Balloon Dilators and that the device is safe for its intended use and patient population.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2004

Mr. Michael A. Patz
Bard Endoscopic Technologies
C. R. Bard, Inc.
129 Concord Road
P.O. Box 7031
BILLERICA MA 01821-7031

Re: K033936
Trade/Device Name: Bard® ELIMINATOR PET® Balloon Dilators
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: 78 KNQ
Dated: December 18, 2003
Received: December 19, 2003

Dear Mr. Patz:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033936

Indications for Use Statement

510(k) Number (if known): ~~TBD~~ K033936

Device Name: Bard® ELIMINATOR® PET Balloon Dilators

Indications For Use: To dilate strictures of the GI tract including the colon, pylorus and esophagus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033936