K013144
1 of 2

OCT 1 9 2001

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 – 4867
Fax:	978 – 262 – 4878
Contact Person:	Marion Gordon, R.A.C.
Date of Preparation:	September 17, 2001

B. Device Name

Trade Name:	Dual Port Wizard™ Low Profile Replacement Gastrostomy Device & Feeding/Decompression Tube
Common/Usual Name:	Feeding Device
Classification Name:	Gastrointestinal tube and accessories

C. Predicate Device Name

Trade Name:	Wizard™ Low Profile Replacement Gastrostomy Device

D. Device Description:
The Wizard™ is a low profile, balloon-type, feeding device designed for percutaneous insertion through an established, appropriately sized stoma tract. The device is held in place by the distal balloon, which remains in situ within the stomach, and an external bolster. Within the bolster are two ports. One side port is used to inflate the retention balloon and the second, surface port mates with the accompanying feeding/decompression tube to administer enteral nutritional fluid or expel gas or gastric contents.

E. Intended Use:
The Dual Port Wizard™ replacement gastrostomy device is indicated for percutaneous placement of a low-profile gastrostomy feeding and decompression device into an established, appropriately sized stoma. The Dual Port Wizard™ Feeding/Decompression Tube (REF 00220W) is the only device which should be

used for feeding, gastric decompression or medication administration with the Dual Port Wizard replacement gastrostomy device.

F. Technological Characteristics Summary:
The fundamental scientific technology of the modified device has not changed. The only dimensional modification to the Wizard™ Low Profile Replacement Gastrostomy Device is related to the mating of an interlocking feeding/decompression tube. The feeding/decompression tube will consist of a proximal dual port adapter, which is friction fitted into a shorter length of the same tubing. The distal 90° adapter is one piece and includes a central stem, which inserts into the feeding port of the modified Wizard™, and a locking lip. All correlating material changes are within the same classification as other cleared feeding tubes.

G. Performance Data
Bench testing, biocompatability, and post risk analysis assessment of the modifications to the Wizard™ demonstrate that design verification/validation activities meet the predetermined acceptance criteria for a safe and effective device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Marion Gordon, R.A.C.
Senior Regulatory Affairs Coordinator
C. R. Bard, Inc.
Bard Endoscopic Technologies
129 Concord Road
P.O. Box 7031
BILLERICA MA 01821-7031

Re: K013144
Trade/Device Name: The Wizard™ Low Profile Replacement Gastrostomy Device
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: September 17, 2001
Received: September 20, 2001

Dear Ms. Gordon:

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 (21 CFR Part 807); 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 the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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"(21 CFR 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,

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

K013144

D. Indications for Use

510(k) Number (if known): ~~TBD~~ K013144

Device Name: Dual Port Wizard™ Low Profile Replacement Gastrostomy Device

Indications For Use: The Dual Port Wizard™ replacement gastrostomy device is indicated for percutaneous placement of a low-profile gastrostomy feeding and decompression device into an established, appropriately sized stoma.

The Dual Port Wizard™ Feeding/Decompression Tube (REF 00220W) is the only device which should be used for feeding, gastric decompression or medication administration with the Dual Port Wizard replacement gastrostomy device.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013144