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SEP 10 1999

Bard Interventional Products Division
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 Interventional Products Division 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:	June 14, 1999

B. Device Name

Trade Name:	Bard® Balloon Inflation System
Common/Usual Name:	Balloon inflation syringe
Classification Name:	21 CFR 876.5980

C. Predicate Device Names

Trade Name:	USCI Presto Disposable Inflation Device Arterial Vascular Engineering, Inc (transferred ownership from C.R. Bard, Inc.) Quantum Inflation Device Wilson-Cook Medical, Inc.

D. Device Description:

The Bard® Inflation System is a disposable, two-piece, plastic 60cc syringe with a cantilevered inflation/deflation lock design and a manometer that is mounted on the distal tip of the syringe barrel.

E. Intended Use:

The inflation system is recommended for use during esophageal, pyloric and colonic balloon dilatation to inflate and deflate balloon dilators and

to monitor the pressure within the balloon.

F. Technological Characteristics Summary:
The Bard® Balloon Inflation System is a hand held device, which includes an inflation syringe and manometer for controlled inflation/deflation of balloons used in GI dilatation.

The Bard® Balloon Inflation System is substantially equivalent to the USCI Presto Disposable Inflation Device and the Wilson-Cook Balloon Inflation Device. All of the manufacturers have designed their respective devices to function in a similar mechanical manner. These inflation systems are hand held devices that infuse fluid, in a controlled manner, to inflate dilatation balloons, and appropriately deflate the balloons post procedure. These designs include a syringe barrel and plunger with a manometer. Inflation/deflation can be achieved in either device by utilizing one of two techniques: (1) pushing/pulling the plunger or (2) turning the plunger in a clockwise/counter clockwise direction.

G. Performance Data
Safe and effective *in vivo* use has been demonstrated with the Bard® Balloon Inflation System since its initial commercialization in 1991.

Accepted scientific methods do exist for assuring the effects of the new characteristics among the Bard, Presto, and Wilson-Cook systems. Comparative bench testing has been evaluated and supports the use of a GI inflation device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1999

Ms. Marion Gordon, R.A.C.
Senior Regulatory Affairs Coordinator
Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031

Re: K991375
Bard® Balloon Inflation System
Dated: June 14, 1999
Received: June 15, 1999
Regulatory Class: II
21 CFR §876.5980/Procode: 78 KNT

Dear Ms. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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. 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): TBD K991375

Device Name: Bard® Balloon Inflation System

Indications For Use: The inflation system is recommended for use during esophageal, pyloric and colonic balloon dilatation to inflate and deflate balloon dilators and to monitor the pressure within the balloon.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991375