MAY 20 1994 K940965

6.0 510(k) SUMMARY FOR THE BARD® BALLOON DILATOR

As required under Section 12, part (a)(i)(3A) of the Safe Medical Device Act of 1990, an adequate summary of any information respecting safety and effectiveness follows.

6.1 General Information

Name and address of submitter:

Interventional Products Division, C.R. Bard, Inc.
200 Ames Pond Drive
Tewksbury, MA 01876

Contact:

John A. DeLucia
Director, Quality Assurance and Regulatory Affairs

Date of Summary:

1 March 1994

Name of Device:

Bard® Balloon Dilator

Predicate Devices:

Bard® Balloon Dilatation System (K863437)
Microvasive Achiever™ (Boston Scientific, Inc.)

Description and Intended Use of Device:

The Bard® Balloon Dilator is a 6Fr. polyurethane 230cm shaft catheter containing a polyethylene terephthalate (PET) balloon. Inflated balloon diameters range in size from 6mm to 18mm. The Bard® Balloon Dilator is intended to be used for dilatation of strictures of the gastrointestinal tract, but not limited to strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.

6.2 Summary of Similarities and Differences

Please refer to Exhibit 6.2 for a Table of Similarities and Differences.

The Bard® Balloon Dilator is a line extension to the currently marketed Bard® Balloon Dilatation System (K863437). Slight design modifications have been made to the predicate Bard® Dilator to expand the product line in order to present a greater selection of dilatation catheters to physicians. These modifications are:

1) extension of the catheter shaft from 180cm to a length of 230cm
2) reduction of the balloon length from 8cm to 4cm
3) modification of balloon geometry and cone angles
4) shorter distal tip
5) alternate supplier of polyurethane for the catheter shaft which contains a different colorant

In all other respects, the proposed device is the similar to the currently marketed Bard® Balloon Dilatation System.

The device subject to premarket notification is also similar to the balloon dilatation catheter, Achiever, Disposable TTS® Balloon Dilator, marketed by Microvasive (Boston Scientific, Inc.). Their catheter length, size, balloon length, inflated diameter, and balloon material are equivalent. The catheter shaft material is different in that the Bard® proposed device consists of polyurethane while the Microvasive Achiever™ is made of polyvinyl chloride.

Table of Substantial Equivalence*

Characteristics	Current Marketed Device Bard® Balloon Dilatation Catheter - K863437	Microvasive Achiever™**	Proposed Bard® Balloon Dilators
Intended Use	For use in the dilatation of strictures of the gastrointestinal tract	same	same
Catheter Length (cm)	180	180 and 240	230
Catheter Size (Fr.)	6	5 - 14	6
Balloon Length (cm)	8	5.5 and 8	4
Inflated Balloon Diameter (mm)	6 - 18	6 - 25	6 - 18
Shaft Material	Polyurethane/Reed Blue Colorant	Polyvinyl Chloride	Polyurethane/Phthalocyanine Blue
Balloon Material	Polyethylene terephthalate	Polyethylene	Polyethylene terephthalate
Lumen	Single	Single	Single

	Balloon Diameter (mm)	Current Marketed Device Bard® Balloon Dilatation Catheter - K863437	Microvasive Achiever™	Proposed Bard® Balloon Dilators
Recommended Maximum Balloon Inflation Pressure (psi)	6	120	75	100
	8	120	60	120
	10	90	50	90
	12	90	50	90
	15	60	45	60
	18	50	35	50

* All dimensions are nominal.

** We could not ascertain the 510(k) number for this device; however, we consider it to be a legally marketed device since it is in commercial distribution.

6.3 Substantial Equivalence Decision Tree

The 510(k) "Substantial Equivalence" Decision-Making Process (Detailed) in ODE Guidance #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence. Please refer to Exhibit 4.2 for a diagram of the 510(k) Decision Tree. The answers to the questions lead to a determination of substantial equivalence

1. **Does the new device have same indication statement?**

   Yes. There is no change in the intended use for the Bard® Balloon Dilatation System as a result of this product line extension. The previously reviewed and currently marketed Bard® Balloon Dilatation Catheter System and its proposed product line extension are intended for use in the dilatation of strictures of the gastrointestinal tract including, but not limited to, strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.

2. **Does the new device have same technological characteristics, e.g. design, materials, etc.?**

   Yes. The proposed Bard® Balloon Dilators like the currently marketed Bard® Balloon Dilatation Catheter System are substantially equivalent with respect to design, in that they consist of a catheter to which an inflatable balloon is bonded to the distal end of the catheter shaft. A slight design modification for the proposed catheters entails longer catheter shafts (180 to 230cm), shorter balloons (4cm), having slightly different cone angles, a shorter distal catheter tip, and a different blue colorant in the polyurethane shaft material.

The proposed design for the product line extension to the Bard® Balloon Dilatation System is also substantially equivalent to the Achiever™ balloon dilator catheters marketed by Microvasive. Microvasive's longest catheter has a usable length of 240cm, the catheter shaft sizes are between 5 and 14Fr, the lengths of the balloon range from 5.5 to 8cm, and the inflated balloon diameters range between 6 and 25mm.

3. **Are the descriptive characteristics precise enough to ensure equivalence?**

Yes. A comparison of the key properties of intended use, design and materials are presented in the "Table of Substantial Equivalence", Exhibit 4.1. This table presents the descriptive and performance data of the currently marketed device, the Bard® Balloon Dilatation System (K863437), the proposed product line extension and Microvasive Achiever™ balloon dilator catheters. The table has been developed to support the performance of the proposed Bard® Balloon Dilatation System product line extension and demonstrates that the proposed Bard dilatation catheters are substantially equivalent to those currently marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

C.R. Bard, Inc.
Bard Interventional Products Division
John A. DeLucia
Director, R.A./Q.A.
200 Ames Pond Drive
Tewksbury, MA 01876

Re: K940965
Trade/Device Name: Bard® Balloon Dilators
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE, KNQ
Dated (Date on orig SE ltr): March 1, 1994
Received (Date on orig SE ltr): March 2, 1994

Dear John A. DeLucia,

This letter corrects our substantially equivalent letter of May 20, 1994.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure