K973013

C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209

JUN 19 1998

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information: C. R. Bard, Inc., Radiology Division
13183 Harland Dr.
Covington, GA 30014

Contact Person: Donna J. Wilson
Contact Person's Address: 8195 Industrial Blvd.
Covington, GA 30014

Contact Person's Telephone: 770-784-6135
Contact Person's FAX: 770-784-6419

Date of Preparation: June 17, 1998

B. Device Name: Opti-Plast® Centurion 5.5F PTA Catheter

C. Predicate Device: Opti-Plast® 5.5F PTA Catheter (#K933483)

Predicate Device for Indications for Use: Medi-Tech® Blue-Max™ Balloon Dilatation Catheter (#K934191)

D. Device Description:

The Opti-Plast Centurion 5.5F PTA Catheter is a dual lumen catheter with a balloon mounted on its distal end. One lumen accommodates the insertion guidewire and the other provides a channel for inflation and deflation of the balloon with contrast media. The catheter is designed to be used in conjunction with a 0.035" diameter guidewire. There are two radiopaque marker bands secured on the catheter body to indicate the position of the balloon within the vasculature. The balloon inflates to the labeled diameter and length at a 10 atmosphere Operating Pressure. The Rated Burst Pressure of the device ranges from 17-20 atmospheres, depending on balloon diameter (see attached table).

E. Indications for Use:

Centurion Peripheral Balloon Dilatation Catheters are recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries, post-deployment dilatation of peripheral vascular stents and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The catheter is not for use in coronary arteries.

F. Technological Characteristics Summary:

Summarized in the attached table.

G. Performance Data:

Bench testing was conducted for the following characteristics: balloon burst strength, balloon distensibility, balloon inflation/deflation time, balloon fatigue, joints and material strength, catheter balloon profile, introducer sheath compatibility, catheter flow rate and maximum injection pressure, deflatability and trackability, tip torque performance, puncture resistance ("toughness"), balloon scratch resistance, balloon fatigue (cycling to rated burst pressure) within a stent and balloon burst within a stent. The test results indicate that the Opti-Plast Centurion 5.5F PTA Catheter is substantially equivalent to the stated predicate device, that there are no new safety or effectiveness issues, and that the device can be utilized for its stated indication.

Technological Characteristics Summary

Features	Proposed Vas-Cath Opti-Plast® *Centurion* 5.5F PTA Catheter	Vas-Cath Opti-Plast® 5.5F PTA Catheter (K933483)	Medi-tech® Blue-Max™ Balloon Dilatation Catheter (K934191)
Indicated Use	PTA of the femoral, iliac and renal arteries, post-deployment dilatation of peripheral vascular stents and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	PTA of vessels of the peripheral vascular system	PTA of the Iliac, Femoral and Renal Arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae
Balloon Material	Nylon	Nylon	Poly-5™
Inflated Balloon Diameters	4 mm - 10 mm	4 mm - 10 mm	4 mm - 10 mm
Inflated Balloon Length	2 cm - 4 cm	2 cm - 10 cm	2 cm - 10 cm
Recommended Operating Pressure	10 atmospheres	6 atmospheres - 8 atmospheres	NA
Rated Burst Pressure	17 atmospheres – 20 atmospheres	8 atmospheres - 12 atmospheres	17 atmospheres
Material for catheter shaft, tip, collar, and extensions	Nylon Co-polymer	Nylon Co-polymer	NA
Coating on shaft	Glissando	None	Medi-Glide
Radiopaque shaft	Yes	Yes	NA
Catheter Shaft Diameter	5.5 French	5.5 French	5.8 French
Shaft Length	50 cm - 140 cm	50 cm - 120 cm	40 cm - 120 cm
Shaft configuration	Double lumen	Double lumen	Double lumen
Marker Bands	Yes, Gold	Yes, Tantalum	Yes, material NA
Tip Length	3 mm	5 mm	5 mm
Guidewire Capability	0.035 inch diameter	0.035 inch diameter	0.035 inch diameter

NA - Not available from promotional literature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 1998

Ms. Donna J. Wilson
Director, Regulatory Affairs
C.R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30209

Re: K973013
Opti-Plast® Centurion 5.5F PTA Catheter
Regulatory Class: II (two)
Product Code: 74 LIT
Dated: March 20, 1998
Received: March 23, 1998

Dear Ms. Wilson:

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 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) 594-4648. 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): #K973013

Device Name: Bard® Opti-Plast® Centurion 5.5 F PTA Catheter

Indications for Use: Centurion Peripheral Balloon Dilatation Catheters are recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries, post-deployment dilatation of peripheral vascular stents and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The catheter is not for use in coronary arteries.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973013/S1