

AUG 25 2005

CONFORMEXX™ Biliary Stent with the PerformMAXX™ Grip
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

As required by the Safe Medical Devices Act of 1990, coded 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 as follows:

General Information:

Submitter Name: Bard Peripheral Vascular, Inc.
Address: 1625 W. Third Street
P.O. BOX 1740
Tempe, AZ 85280-1740

Telephone Number: (480) 894-9515
Fax Number: (480) 449-2546

Contact Person: Dennis Salzmann, Ph.D.
Manager, Regulatory Affairs

Device Information:

Device Trade Name: **CONFORMEXX™ Biliary Stent with the PerformMAXX™ Grip**
Common/Usual Name: Biliary Stent
Classification: Class II
Classification Panel: Gastroenterology/Urology

Predicate Device:

CONFORMEXX™ Biliary Stent and Delivery System (K021994, cleared January 2, 2003)

Summary of Change:

The design modifications to the CONFORMEXX™ Biliary Stent and Delivery System are addition of the PerformMAXX™ Grip, an additional delivery system length, and modification of the packaging. These changes result in a subject device that provides more deployment methods and delivery system length options for physicians. All other aspects of the subject device remain the same as the predicate devices.

Device Description:

The Bard® CONFORMEXX™ Biliary Stent with the PerforMAXX™ Grip is a stenting device designed to maintain the patency of biliary ducts obstructed by malignant neoplasms. The device includes the self-expanding Nitinol CONFORMEXX™ Stent preloaded on a flexible, multifunctional stent deployment system, the BARD S.A.F.E.™ Delivery System with the PerforMAXX™ Grip. It is preloaded into the delivery system and is available in two delivery system lengths, and various device diameters and lengths.

Intended Use of Device:

The Bard® CONFORMEXX™ Biliary Stent with the PerforMAXX™ Grip is intended for palliation of malignant strictures in the biliary tree.

Technological Comparison to Predicate Device:

The technological characteristics of the Bard® CONFORMEXX™ Biliary Stent with the PerforMAXX™ Grip are substantially equivalent to those of the predicate Bard® CONFORMEXX™ Biliary Stent and Delivery System in terms of intended use, application, user population, basic design, performance, labeling, and sterilization method.

Non-Clinical Performance Data:

Design verification and validation of the modified device was done with conformance to or evaluated based on the following FDA guidance document:

Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents, February 5, 1998.

All test results confirm the modified device to be substantially equivalent to the predicate devices.

Conclusions:

The Bard® CONFORMEXX™ Biliary Stent with the PerforMAXX™ Grip met all the predetermined performance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Bard® CONFORMEXX™ Biliary Stent with the PerforMAXX™ Grip is substantially equivalent to the legally marketed predicate device, the Bard® CONFORMEXX™ Biliary Stent and Delivery System.



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Dennis Salzmann, Ph.D.
Manager, Regulatory Affairs
Bard Peripheral Vascular, Inc.
1625 W. Third Street
P.O. Box 1740
TEMPE AZ 85280-1740

Re: K052114

Trade/Device Name: Bard® CONFORMEXX™ Biliary Stent with the
PerforMAXX™ Grip

Regulation Number: 21 CFR §876.5010

Regulation Name: Biliary catheter and accessories

Regulatory Class: II

Product Code: FGE

Dated: August 2, 2005

Received: August 4, 2005

Dear Dr. Salzmann:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052114

Device Name: Bard® CONFORMEXX™ Biliary Stent with the
PerforMAXX™ Grip

Indications For Use:

The Bard® CONFORMEXX™ Biliary Stent with the PerforMAXX™ Grip is indicated for the treatment of biliary strictures resulting from malignant neoplasms.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052114

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