

C.R. Bard, Inc.  
Regulatory Affairs  
129 Concord Road  
P.O. Box 566  
Billerica, MA 01821  
508-667-2511  
FAX: (508) 667-8594

K971034

MAY 28 1997



## VI. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

### A. Submitter Information:

Name: USCI Division of C.R. Bard, Inc.  
Address: 129 Concord Road, Billerica, MA 01821  
Phone: (508) 667-2511 extension 1065  
Fax: (508) 667-8594  
Contact Person: Douglas E. Ferguson  
Senior Regulatory Affairs Coordinator  
Date of Preparation: March 17, 1997

### B. Device Name

Trade Name: USCI® Mainstay Guiding Catheter  
Common Name: Guiding Catheter  
Classification Name: Diagnostic Intravascular Catheter/Percutaneous Catheter

### C. Predicate Device Name(s):

1. Scimed Guiding Catheters
2. USCI Guiding Catheters

### D. Device Description

The Mainstay catheter is a guiding catheter for use in the cardiovascular system.

### E. Intended Use

Guide catheters provide a pathway through which dilatation systems and other interventional devices are introduced.

### F. Technological Characteristics Summary

The USCI Mainstay Guiding Catheter is very similar to the Scimed guiding catheters regarding materials and construction, and is similar to the USCI Illumen-8 guiding catheter regarding packaging and sterilization.

The indications for use are similar to both the Scimed catheters and the USCI guiding catheters. They are all indicated to provide a pathway through which dilatation systems and other interventional devices are introduced. The proposed Mainstay indications are:

USCI® guiding catheters are designed for use in the cardiovascular system. Their primary function is to provide a pathway through which dilatation systems and other interventional devices are introduced. Guiding catheters also allow pressure monitoring and injection of contrast agents.

Similar to both the Scimed catheters and the USCI catheters, the USCI Mainstay catheter will be available in 6 French - 9 French, and will be offered in various curve styles.

#### G. Performance Data

Safety and performance testing was performed to demonstrate that the USCI Mainstay Guiding Catheter is substantially equivalent to the predicate devices.

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 28 1997

Mr. Douglas E. Ferguson  
USCI Division of C.R. Bard, Inc.  
129 Concord Road  
Billerica, Massachusetts 01821

Re: K971034  
USCI® Mainstay Guiding Catheter  
Regulatory Class: II (two)  
Product Code: 74 DQO  
Dated: March 20, 1997  
Received: March 21, 1997

Dear Mr. Ferguson:

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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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.

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

Enclosure

**D. INDICATIONS FOR USE**

Device Name: USCI® Mainstay Guiding Catheter

**Indications for Use:**

USCI® guiding catheters are designed for use in the cardiovascular system. Their primary function is to provide a pathway through which dilatation systems and other interventional devices are introduced. Guiding catheters also allow pressure monitoring and injection of contrast agents.

**Contraindications:**

These devices are not intended for use in the cerebral vasculature.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K971034

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

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Premarket Notification for USCI Mainstay Guiding Catheter