

K961135

**USCI Division**  
C.R. Bard, Inc.  
Clinical and Regulatory Affairs  
1200 Technology Park Drive  
P.O. Box 7025  
Billerica, MA 01821  
(508) 667-1300  
FAX: (508) 670-4326



## **SECTION 6.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

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:**

USCI Division of C.R. Bard, Inc.  
1200 Technology Park Drive  
Billerica, MA 01821

◆ **Contact:**

Robert T. Miragliuolo  
Director, Regulatory Affairs

◆ **Date of Summary:**

March 20, 1996

◆ **Name of Device:**

USCI® Input® 10F/11F Percutaneous Arterial/Venous Catheter Introducer Set

◆ **Common/Usual Name of Device:**

Catheter Introducer

◆ **Device Classification:**

Cardiopulmonary Bypass Adapter, Stopcock, Manifold or Fitting

◆ **Predicate Devices:**

USCI® Input™ Introducer Set (K940092, concurrence received August 10, 1995); referred to as Input SC in this submission for identification purposes.  
Daig 11F Introducer

102

◆ **Description and Intended Use of Device:**

Input 10F/11F consists of an introducer sheath (uncoated), a locking dilator (may contain a single or double dilator), and a guide wire. These components are presented in Exhibit 3.1 of this section with the exception of the guide wire since there are no changes to this sub-assembly. Refer to Exhibit 3.3 in this section for a photograph of the Input 10F/11F introducer.

The components described in this submission are equivalent to those mentioned in the USCI Input Introducer with Sit-Up Claim (termed Input SC in this submission for identification purposes), 510(k) #K940092. The FEP sheath and black PE materials, although new to the Input Introducer line of products, are not new to USCI. These materials are used in various other USCI introducers such as the Hemaquet Introducer (K781954/concurrence received November 29, 1978) and the Hemaflex Introducer (K897041/concurrence received March 16, 1990). Both the Hemaquet and Hemaflex Introducers have a black PE dilator. The Hemaquet Introducer also contains the FEP sheath with the polyurethane strain relief.

Input 10F/11F are indicated as percutaneous introducers that are used to facilitate placing a catheter through the skin into a vein or artery. Input 10F/11F are recommended for initial percutaneous introduction of a closed end catheter, temporary pacing electrode catheter or probe, or a balloon catheter. They may also be used as an instrument to exchange catheters during a procedure. This indication statement is identical to the indication provided in the Input SC 510(k) #K940092.

The Input SC (K940092), the predicate device, consists of an introducer sheath (hydrophilic coated), a locking dilator (that may contain a single or double dilator), and a guide wire. Certain model numbers also contain a locking obturator. The Input 10F/11F, covered under this 510(k), will not include a locking obturator.

The current Input SC (as described in K940092, concurrence received August 10, 1995) allows the patient to sit up in bed at a 60° angle, post-PTCA procedure. A statement and illustration was added to the Instructions for Use (IFU) that advises physicians that patients may sit up-right (up to a 60° angle) post-procedure. However, the IFU for the Input 10F/11F introducer will not include the option of allowing the patient to sit up in bed at a 60° angle, post-PTCA procedure

Input 10F/11F are indicated as percutaneous introducers that are used to facilitate placing a catheter through the skin into a vein or artery. Input 10F/11F are recommended for initial percutaneous introduction of a closed end catheter, temporary pacing electrode catheter or probe, or a balloon catheter. They may also be used as an instrument to exchange catheters during a procedure.