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DEC 12 1995

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
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◆ **Contact:**

Robert T. Miragliuolo
Director, Regulatory Affairs

◆ **Date of Summary:**

December 18, 1995

◆ **Name of Device:**

USCI® Input® TS and Input TL Percutaneous Arterial/Venous Catheter Introducer Set

◆ **Common/Usual Name of Device:**

Catheter Introducer

◆ **Device Classification:**

Cardiopulmonary Bypass Adapter, Stopcock, Manifold or Fitting

◆ **Predicate Device:**

USCI® Input™ Introducer Set (K940092, concurrence received August 10, 1995)

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

Input TS & TL consists of an introducer sheath (uncoated), a locking dilator (may contain a single or double dilator), and a guide wire. Certain model numbers will also contain a locking obturator. These components are presented in Section 3.0, Exhibit 3.2. The components described in this submission are equivalent to those mentioned in the USCI Input Introducer Set, 510(k) #K940092. The latex gasket, teflon sheath with polyurethane strain relief and black PE materials, although new to the Input Introducer line of products, are not new to USCI. These materials are currently used in various other USCI introducers such as the Hemaquet Introducer (K781954/concurrence received November 29, 1978) and the Hemaflex Introducer (K915553/concurrence received February 21, 1991). Both the Hemaquet and Hemaflex Introducers have a latex gasket, a teflon sheath with a polyurethane strain relief and a black PE dilator.

The Input Introducer Set (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.

Input TS & TL are indicated as percutaneous introducers that are used to facilitate placing a catheter through the skin into a vein or artery. Input TS & TL 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 Introducer Set 510(k) #K940092.

During cardiac catheterization laboratory procedures, through either angiographic diagnostic or angioplasty therapeutic approaches, a physician may elect to leave an introducer in place (within the vessel). The current practice is for patients to lay flat on their backs for several hours post-PTCA. Without the support of a catheter the introducer sheath may collapse or kink. This introducer kit supplies an obturator (the obturator is also supplied as an individual component) to be used as a means of support while the introducer remains in place. The obturator material is flexible, thereby allowing the patient to sit-up in bed in the Semi-Fowler position (up to a 60° angle) post-PTCA rather than lying flat. Allowing the patient to sit up in bed at a 60° angle has the potential to enhance their comfort.

The current Input Introducer Set (predicate device), with a pebax sheath, was described in K940092 (concurrence received August 10, 1995) as a device which allows for this alternative post-PTCA patient care procedure. A statement and illustration was added to the Instructions for Use that advises physicians that patients may sit up-right (up to a 60° angle) post-procedure. The devices covered under this 510(k) Premarket Notification, with a teflon sheath, will include the same statement and illustration.

Input TS & TL contains an obturator to be used as a means of support while the introducer remains in place.

These devices are supplied sterile and are intended for one time use only.