K960056

**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

OCT 23 1996

USCI

**Section VI. 510(k) Summary of Safety and Effectiveness Information**

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

VI. A. General Information

- Name and address of submitter:

  USCI Division, C.R. Bard, Inc.
  1200 Technology Park Drive
  P.O. Box 7025
  Billerica, MA 01821
  Phone #: (508)667-1300
  Fax #: (508)670-4301

- Contact:

  Robert T. Miragliuolo
  Director of Regulatory Affairs

- Date of Summary: January 2, 1996

- Trade Name of Devices:

  USCI® Pro-Flo® Angiographic Catheter
  USCI® Pro-Flo® XT™ Angiographic Catheter
  USCI® Pro-Flo® with Soft Tip Angiographic Catheter
  USCI® Pro-Flo® XT™ with Soft Tip Angiographic Catheter

  Common/Usual Name: Cardiovascular Angiographic Catheter

  Classification Name: Diagnostic, Intravascular Catheter

- Trade Name of Predicate Devices:

  USCI® Positrol-II® Angiographic Catheter
  Cordis® Super Torque Plus® Angiographic Catheter

- Description and Intended Use of Device:

  The USCI® Pro-Flo, Pro-Flo with Soft Tip, Pro-Flo XT and Pro-Flo XT with Soft Tip are diagnostic intravascular catheters used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.



BARD

VI. B. Summary of Similarities and Differences

The USCI Pro-Flo and Pro-Flo XT catheters are substantially equivalent to the USCI Positrol-II and Cordis ST Plus catheters. The USCI Pro-Flo and Pro-Flo XT catheters are also commercialized with a soft tip feature. The primary difference between these catheters and the standard Pro-Flo and Pro-Flo XT catheters is that the tip of the catheter is made of a softer polyurethane material called Tecoflex. This soft-tip feature received FDA concurrence in 1988 through the premarket notification submission for the USCI Soft Tip Angiographic Catheter (#K883051, FDA Concurrence date: October 6, 1988). All of the catheters are currently marketed. A table of similarities and differences between these catheters is presented in Exhibit VI.1.

The general design, functionality, and indications for use of the USCI PF and PF XT catheters are equivalent to the USCI P-II and Cordis ST Plus catheters. All four catheters have the same principles of operation. They are used to measure intracardiac pressures, sample blood, and introduce substances into the heart and vessels. They are introduced into femoral or brachial arteries and advanced under fluoroscopic guidance to just past the orifice of the right or left ventricle. Radiopaque contrast medium is injected through the catheter so that the blood vessels and/or cardiac chambers can be visualized with fluoroscopy. The differences between the PF/PF XT catheters and the P-II catheters, as presented in Exhibit VI. 1, are:

**VI.B.1. PRO-FLO CATHETER**

1. a. The difference between the PF and P-II catheters is in the durometer of the polyurethane used in the inner sleeve of the PF line.

1. b. The range of outer diameters are different. The Pro-Flo catheters are available in the 6F and 7F sizes as compared to the 7F and 8F sizes for the Positrol-II catheters.

**VI.B.2. PRO-FLO XT CATHETER**

2. a. The Pro-Flo XT catheter differs from the Positrol-II catheter in the durometer of polyurethane used in the outer jacket of the shaft of the catheter.

2. b. The Pro-Flo XT catheter is also sold in the 6F and 7F sizes as compared to the 7F and 8F sizes for the P-II catheter.

2. c. The colorants vary between the PF XT and the PF/P-II catheters for market differentiation. PF XT and PF XT ST are marketed with a blue colorant whereas PF, PF ST and P-II catheters are marketed with a green colorant.

**VI.B.3. PF/PF XT CATHETERS WITH SOFT TIP (PF ST AND PF XT ST):**

A soft-tip feature was made available in 1989 to the **Pro-Flo XT and Pro-Flo** line of catheters. The primary difference between these catheters and the standard Pro-Flo and Pro-Flo XT catheters was that the tip of the catheter is made of a softer polyurethane material. The addition of this soft-tip feature on a USCI polyurethane angiographic catheter received FDA concurrence in 1988 through the premarket notification submission for the USCI Soft Tip Angiographic Catheter (#K883051, FDA Concurrence date: October 6, 1988).

**VI.B.4. ENHANCED PERFORMANCE PF and PF XT CATHETERS:**

The **Enhanced Performance Pro-Flo and Pro-Flo XT** catheters were introduced in 1992 through a regulatory "No-510(k) file" decision. The reason for introduction of these enhanced performance catheters was to maintain and grow market share. The term "enhanced performance" was a marketing term, referring to this perceived improvement in torque response by some customers. The wire braiding of the 6F PF/PF ST and PF XT/PF XT ST catheters was changed. Also, the JR4 tip segment length (6F/7F PF/PF ST and PF XT ST catheters) and curve style (6F/7F PF/PF ST catheters) were changed to enhance perceived torque response of the PF and PF XT catheters.

**VI.B.5. RADIOPAQUE MARKERS:**

The presence of radiopaque markers to the PF, PF XT, PF ST and PF XT ST angiographic catheters will be a feature intended for estimation of ventricular volume. Currently, radiopaque markers are offered only on the PF catheters. In the future,

however, they will be introduced on the PF ST, PF XT and PF XT ST catheters. Multi-radiopaque pacing bands previously received FDA concurrence (March 5, 1981) on USCI premarket notification submission, #K810412. The 510(k), #K810412, requested FDA concurrence for the addition of radiopaque markers on USCI's P-II and Nycore angiographic catheters. In addition, radiopaque markers were on older USCI Class III devices such as the Profile Plus PTCA balloon catheter (P790017/S8, FDA approval 10/7/86) and the LPS/LPS II PTCA balloon catheters (P790017/S11, FDA approval 6/15/87).

VI. 3. Substantial Equivalence Decision Tree

The 510(k) "Substantial Equivalence" Decision-Making Process (Detailed in ODE Guidance #K86-3) Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence. Please refer to Exhibit VI.2 for a diagram of the 510(k) Decision Tree. The answers to the questions lead to a determination of substantial equivalence.

The first question asks, **"Does New Device Have Same Indication Statements?"** The answer is **"Yes"**.

The USCI Pro-Flo, USCI Pro-Flo XT, USCI P-II and Cordis ST Plus catheters are intravascular diagnostic catheters used to record intracardiac pressures, sample blood, and introduce substances into the heart and vessels. A soft-tip feature was made available in 1989 to the **Pro-Flo XT and Pro-Flo** line of catheters. The primary difference between these catheters and the standard Pro-Flo and Pro-Flo XT catheters was that the tip of the catheter is made of a softer polyurethane material. The addition of this soft-tip feature on a USCI polyurethane angiographic catheter received FDA concurrence in 1988 through the premarket notification submission for the USCI Soft Tip Angiographic Catheter (#K883051, FDA Concurrence date: October 6, 1988).

The second question asks, **"Does New Device Have Same Technological Characteristics, e.g., Design, Materials, Etc?"** The answer is **"Yes."**

The USCI Pro-Flo and Pro-Flo XT catheters have the same technological characteristics as the USCI Positrol-II catheters. The designs are similar; all three catheters have polyurethane shaft and tip segments with the shaft comprising of an inner jacket of polyurethane, a stainless steel braid

and an outer jacket of polyurethane. The soft tip segments are comprised of a softer polyurethane material and are bonded onto the shaft segment for PF ST and PF XT ST catheters.

The third question asks, **"Are The Descriptive Characteristics Precise Enough to Ensure Equivalence?"** The answer is **"No."**

Descriptive characteristics would not be precise enough to ensure equivalence. The differences in durometers of the polyurethane used in the USCI PF/PF XT and the P-II catheters result in minor differences not only in the dimensions of the diameter of the shaft but also in the stiffness feature of the finished product. While dimensions may be measured and differences in durometer of polyurethane described, the differences in stiffness is a performance characteristic of the device and hence, cannot be described in a precise manner.

The fourth questions asks, **"Are Performance Data Available to Assess Equivalence?"** The answer is **"Yes."**

Performance test results are available to assess the equivalence of the PF, PF ST, PF XT and PF XT ST catheters to the predicate devices. The tests that were conducted include the shaft stiffness, shaft torque, shaft burst and tensile (soft tip, tip joint and hub/shaft) tests.

The fifth question asks, **"Performance Data Demonstrate Equivalence?"** The answer is **"Yes."**

As indicated by test results, performance data demonstrate equivalence of the USCI PF, PF ST, PF XT and PF XT ST catheters to the predicate devices.