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**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:**  
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- ◆ **Contact:**  
Deborah L. Herrington  
Senior Regulatory Affairs Coordinator
- ◆ **Date of Summary:**  
April 1, 1996
- ◆ **Name of Device:**  
USCI® Commander™ Series Guide Wires
- ◆ **Common/Usual Name of Device:**  
Catheter Guide Wire for PTCA Catheter
- ◆ **Device Classification:**  
21 CFR 870.4290

◆ **Predicate Device:**

USCI® Phantom™ Guide Wire (concurrence received June 20, 1989, K890505)

USCI® LumiSilk Guide Wire (concurrence received March 1, 1993, K925074/A)

USCI® Standard Guide Wire (approval received October 7, 1986, P790017/S8)

Interventional Technologies Inc. 0.014" Tec Guide Wire (concurrence received May 23, 1989, K890515)

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

The Commander Series Guide Wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. The Commander Series guide wires are not intended for use in the cerebral vasculature. Commander steerable exchange guide wires are used to facilitate the substitution of one diagnostic or interventional device for another.

## **6.2 Summary of Similarities and Differences**

The proposed Commander guide wire family is substantially equivalent to the USCI Phantom Guide Wire (known at the time of filing as the Grey/Black Guide Wire, K890505, concurrence received June 20, 1989). Both wires have the same indications for use in that they are both utilized with USCI Dilatation Catheters. The wording is expanded for the Commander guide wire so that it more clearly identifies the uses of the device: "for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion." Since concurrence was received for the Phantom wire in 1989, technology has progressed so that the indications for the Commander guide wire have replaced the phrase "USCI Dilatation Catheters" with "interventional devices" to acknowledge the use of atherectomy devices and balloons that support stents.

The Commander guide wire is substantially equivalent to the Phantom guide wire with respect to the design. Both wires contain a hypotube, core wire, spring segment and tip.

### 6.3 Substantial Equivalence Decision Tree

The 510(k) "Substantial Equivalence" Decision Making Process (detailed) in ODE Guidance Memo #K86-3 was utilized to make a determination of substantial equivalence. The answers to these questions lead to a determination of substantial equivalence.

1. Does New Device Have Same Indication Statements?

No. The indications for use for the Commander guide wire have been expanded. Since concurrence was received for the Phantom wire in 1989, technology has progressed so that the indications for the Commander guide wire have replaced the phrase "USCI Dilatation Catheters" with "interventional devices" to acknowledge the use of atherectomy devices and balloons that support stents. This change is consistent with the indication for use included with the 0.014" Tec guide wire from InterVentional Technologies Inc. (K890515). The indication for the Tec wire is as follows: "The InterVentional Technologies Inc. 0.014" Guide Wire is recommended for use to facilitate the navigation and placement of atherectomy and angioplasty interventional catheters through tortuous coronary and peripheral vessels."

2. Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (in Deciding, May Consider Impact on Safety and Effectiveness)?

No. The therapeutic/diagnostic effect of the Commander guide wire is "for introduction and placement of diagnostic or interventional devices" which is consistent with the intended therapeutic/diagnostic effect of currently marketed guide wires. The location of the "therapeutic/diagnostic effect" has been expanded to include the peripheral vasculature. There are no new safety or effectiveness concerns raised with the addition of the peripheral vasculature; the same concerns as the coronary vasculature apply here also.

3. Does New Device Have Same Technological Characteristics, e.g. Design, Materials, etc.?

No. Although the basic five segments of the Commander guide wire are similar to other currently marketed devices, the Commander guide wire contains radiopaque markers (referred to as Accumarkers).

4. Could the New Characteristics Affect Safety or Effectiveness?

**No.** All materials utilized during manufacture of the Commander guide wire are identical to a currently marketed device, including the material of the markers. The use of markers is not new to the medical device industry. Radiopaque markers are currently present in balloon dilatation catheters. Exit markers that indicate location are present on PTCA guiding catheters. The markers on the Commander guide wire are contained within the spring; therefore, there is no exposure to the patient and they do not affect the performance characteristics of the device.

5. Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

**No.** Although the Commander guide wire has been described in detail in Section 3.0, it may be difficult to determine how the device in its many different sub-families will perform.

6. Are Performance Data Available to Assess Equivalence?

**Yes.** Each sub-family of the Commander guide wire has been tested along with a device of similar performance characteristics. Refer to Appendix B in Volume II. In addition to the Phantom guide wire, the Lumisilk guide wire and the Standard guide wire, the TEC guide wire from IVT was tested due to the stiffness characteristics of the core wire.

7. Performance Data Demonstrate Equivalence?

**Yes.** Refer to Appendix B in Volume II for the results of the *in vitro* testing of the Commander guide wire and the predicate devices.

Based on the FDA decision tree, USCI considers the Commander guide wire to be substantially equivalent to the Phantom guide wire.