

**6.0 510(k) SUMMARY FOR THE TIGER™ GUIDEWIRE**

K962178

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:**

Bard Interventional Products Division, C.R. Bard, Inc.  
129 Concord Road  
Billerica, MA 01821-7031

- **Contact:**

Beth A. Rochette  
Regulatory Affairs Manager

- **Date of Summary:**

June 6, 1996

- **Name of Device**

Bard® Tiger™ Guidewire

- **Predicate Device(s):**

Boston Scientific Zebra™ Exchange Guidewire, Flexmedics FlexFinder Guidewire, and Davol Laparoscopic Suction Irrigation Probe.

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

The Bard® Tiger™ guidewire is indicated for use with devices having a .035" guidewire compatible lumen. The Tiger guidewire is designed to guide and exchange endoscopic accessories into the G.I. Tract, including, but not limited to, the common bile, cystic, the right, and left hepatic and pancreatic ducts. It is not necessary to withdraw or remove the Tiger guidewire during sphincterotomy.

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## 6.2 Summary of Similarities and Differences

The Tiger™ guidewire is substantially equivalent to the currently marketed Boston Scientific Zebra™ exchange guidewire (K931650) and the Flexmedics Corporation FlexFinder guidewire (K923755). The tapered core material is the same as the Davol Laparoscopic Suction Irrigation Probe (K941334), which received concurrence on June 14, 1994.

The general design, and functionality of the Tiger guidewire is similar to the Boston Scientific Zebra exchange guidewire and the broader GI indication of the Flexmedics Corporation FlexFinder guidewire. All three of the guidewires have similar principles of operation. The guidewires are used to guide and exchange endoscopic accessory devices through the biopsy channel of an endoscope into the GI tract and to aid in selective cannulation of the biliary ductal system under endoscopic visualization or fluoroscopy. The major differences between the guidewires are:

1. The Tiger guidewire core material is a composite of Bisphenol A Epoxy and fibers, while the Zebra exchange and FlexFinder guidewires are constructed of Nitinol.
2. The Tiger guidewire jacket material is polyethylene, while the Zebra exchange and FlexFinder guidewires are constructed out of the following plastics: Fluoropolymer, Urethane, and polyester.

The Bisphenol A Epoxy and fibers, commonly known as fiberglass, used in the proposed Tiger guidewire is the same material utilized with the Davol Laparoscopic Suction Irrigation Probe tip. The Davol Laparoscopic Suction Irrigation Probe is a nonconductive fiberglass probe intended for suction and irrigation of the operative site during electrosurgical laparoscopic procedures. The probe tip is advanced to the desired location through a laparoscopic cannula under endoscopic visualization. All three guidewires have a plastic jacket, however, the jacket material of the Tiger guidewire is a slightly different polymer than used in the Zebra exchange and FlexFinder guidewire. Biocompatibility testing has confirmed the material is safe for contacting mucosa and tissue. Both of these materials were chosen for their strength and nonconductive properties.