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BARD

6.0 510(k) SUMMARY FOR THE BARD® DIRECTOR™ GUIDEWIRE

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:

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- Date of Summary:

  November 15, 1996

- Name of Device:

Trade Name:	Bard® Director™ Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Endoscope and accessory

- Predicate Device(s):

  Microvasive® Geenen Endotorque™ Guidewire
  Wilson-Cook® Tracer™ Wire Guide
  Davol® Laparoscopic Suction Irrigation Probe

- Description and Intended Use of Device:

  For use with devices having a .035" guidewire compatible lumen. The Director guidewire is used to guide endoscopic accessories into the GI tract and for cannulation of the pancreatobiliary ducts.

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6.2 Summary of Similarities and Differences

The Bard ®Director™ Guidewire is substantially equivalent to the currently marketed Microvasive® Geenen Endotorque™ Guidewire (#K942677/A), the Wilson-Cook® Tracer™ Wire Guide (#K910497), and the Davol® Laparoscopic Suction Irrigation Probe (#K941334).

The indication statements are different, however, the Director guidewire has the same intended use as the Geenen Endotorque guidewire and the Tracer wire guide. The Director guidewire is used to guide endoscopic accessories into the GI tract and for cannulation of the pancreatobiliary ducts. The general design and functionality of the Director guidewire is similar to these devices. All three of the guidewires are advanced through a duodenoscope (side viewing endoscope) under endoscopic and/or fluoroscopic visualization into the GI tract to the desired location. The major differences between the guidewires are:

The Director guidewire is constructed with three core segments that are bonded together. The proximal core is a Bisphenol A epoxy with fibers, covered with a polyethylene jacket, the mid section of the guidewire is a PTFE coated stainless steel, and the distal section is a nitinol tapered core covered with a polyester weave, polyurethane, and proprietary hydrophilic coating. Both the Geenen Endotorque guidewire and the Tracer wire guides have a single nitinol distal tapered core with a teflon jacket and a distal tip coating for lubricity.

Although the materials and construction are different; these materials are used in currently marketed devices. The Bisphenol A epoxy used in the proposed Director 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. PTFE and stainless steel are standard materials used in the manufacturing of guidewires. The jacket material covering the distal tapered nitinol core is different from the Geenen Endotorque and the Tracer wire guide, however, biocompatibility testing has confirmed the materials are safe for contacting mucosa and tissue.

The distal tapered core with the polyurethane coating provides a kink resistant, radiopaque, lubricious guidewire. Stiffness, torque, and radiopacity bench testing has confirmed the device is substantially equivalent to the Microvasive Geenen Endotorque™ guidewire and the Wilson-Cook Tracer™ wire guide.