K963484

P104

NOV 19 1996

Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
508-663-8989

BARD

6.0 510(k) SUMMARY FOR THE BARD®HIGH FLOW PAPILLOTOME

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
  Phone: (508) 663-8989
  Fax: (508) 670-9827

- Date of Summary:

  August 12, 1996

- Name of Device:

Trade Name:	Bard® High Flow Papillotome
Common/Usual Name:	Papillotome
Classification Name:	Endoscopic Electrosurgical Accessory

- Predicate Device(s):

  Bard ProForma Papillotome and the Microvasive® (Boston Scientific Corp.) Fluorotome™/Ultratome™/Ultratome XL Sphincterotomes

K963484

P204

- Description and Intended Use of Device:

The Bard High Flow papillotome is indicated for use in transendoscopic papillotomy of the Papilla of Vater and/or the Sphincter of Oddi under endoscopic and/or fluoroscopic visualization.

K963484

P3 of 4

6.2 Summary of Similarities and Differences

The High Flow papillotome is substantially equivalent to the currently marketed Bard® Proforma Papillotome (#K894861) manufactured by Wiltek Medical, Inc. and the Microvasive® (Boston Scientific Corporation) Sphincterotomes, which received concurrence through #K930022.

The indications for use of the High Flow papillotome are equivalent to both the Bard Proforma papillotome and the Microvasive sphincterotomes. The general design and functionality of the High Flow papillotome are similar to these currently marketed devices. All three of the papillotomes are advanced with or without a guidewire through the biopsy channel of a side viewing endoscope under endoscopic and/or fluoroscopic visualization and a diathermic current is applied to the cutting wire to incise the Papilla of Vater and/or the Sphincter of Oddi. The major differences between the papillotomes are:

1. The High Flow papillotome dual lumen shaft is constructed out of nylon with a MDX silicone coating, while both the Bard Proforma papillotome and the Microvasive sphincterotomes use PTFE. Comparative movement testing through a side viewing endoscope and guidewire movement testing has demonstrated substantial equivalence.

2. The High Flow papillotome uses a different plastic material for both the luer fitting and the handle assembly. The High Flow papillotome luer fitting is PVC and the handle assembly material is ABS; the Bard Proforma papillotome uses polycarbonate for both of these components.

3. The High Flow papillotome electrode assembly is similar in construction to the Bard Proforma except that the set screw is stainless steel versus nickel plated brass. Electrical testing has confirmed the High Flow papillotome meets the requirements of the ANSI/AMMI HF18-1993 standard.

4. The High Flow papillotome shaft is an 8 french O. D. that tapers to a 5.5 french tip O. D. The currently marketed papillotomes are labeled as either a 5 Fr., 7.5 Fr. or a 7 Fr. that tapers to a 5.5 Fr. O.D.

K963484

p4/4

Although some of the materials used for the High Flow papillotome are different from the Bard Proforma and Microvasive sphincterotomes they are commonly used materials in the medical device industry. Biocompatibility testing has confirmed the materials used for the proposed High Flow papillotome are safe for contacting mucosa and tissue.

The larger O. D. of the High Flow papillotome shaft provides a slightly larger guide lumen for accessory devices and contrast medium injection. In Vitro flow testing has confirmed the device is substantially equivalent to the Microvasive® Ultratome XL sphincterotome.

In addition, bow force, bow orientation, radiopacity and joint integrity tests were completed to confirm device safety and effectiveness.