

**Bard Interventional Products Division**

C.R. Bard, Inc.  
129 Concord Road  
P.O. Box 7031  
Billerica, MA 01821-7031  
978-663-8989



**VI 510(k) SUMMARY FOR THE BARD® ProForma™ and Apollo<sup>3</sup>™**

**PAPILLOTOMES**

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (l)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

**A. General Information**

- Name and address of submitter:  
Bard Interventional Products Division, C.R. Bard, Inc.  
129 Concord Road, Building 3  
Billerica, MA 01821
  
- Contact:  
Marion Gordon R.A.C.  
Senior Regulatory Affairs Coordinator  
Telephone (978) 262-4867  
Fax (978) 262-4878
  
- Date of Summary:  
July 21, 1998
  
- Name of Device:
 

Trade Name:	Bard® ProForma™ and Apollo <sup>3</sup> ™ Papillotomes
Common/Usual Name:	Papillotome
Classification Name:	Endoscopic electrosurgical unit and accessories

- Predicate Device: Wiltek Papillotome  
Wiltek Medical, Inc.
  
- Description and Intended Use of Device:  
The Bard® ProForma™ and Apollo<sup>3</sup>™ Papillotomes are designed and recommended for transendoscopic cannulation and sphincterotomy of the Papilla of Vater and/or Sphincter of Oddi. A papillotome is placed under direct vision of a side-viewing duodenoscope, with or without fluoroscopic aid. Both the double lumen and triple lumen designs will have a variety of precurved tip configurations and cutting wire lengths. The Bard papillotomes are compatible with a 0.035 inch O.D. guidewire.

**B. Summary of Similarities and Differences**

The Bard® ProForma™ and Apollo<sup>3</sup>™ Papillotomes are substantially equivalent to the following legally marketed papillotomes manufactured by Wiltek Medical, Inc. (K894861) and commercialized under the trade names of:

- Accuratome<sup>3</sup>™, Accuratome™, and Double Lumen™ Papillotome

**Similarities**

The Bard® ProForma™ and Apollo<sup>3</sup>™ Papillotomes have equivalent intended uses as the Wiltek papillotomes. The general design characteristics and functionality are also similar. They all have a one (1) piece system construction which includes a handle, either double or triple lumen shafts, various cutting wire lengths and construction with precurved tips in multiple lengths.

Both the Wiltek and Bard devices may be advanced with or without using an .035 inch guidewire through the biopsy channel of a duodenoscope with optional use of fluoroscopy. A diathermic current is applied through the cutting wire to incise the Papilla of Vater or Sphincter of Oddi. A Touhy Borst may be attached to the guidewire lumen of the double lumen device to assist in placement and minimize

contrast leakage.

### **Differences**

The major design difference between the Bard and Wiltek papillotomes is the ProForma™ and Apollo<sup>3</sup>™ will have an ergonomic handle made from ABS instead of the polycarbonate handle used in the Wiltek design. The precurved tips on the Bard papillotomes will be either beveled or tapered, where the Wiltek tips are only beveled. A full range of tip lengths, from 8mm to 20mm, are provided by both manufacturers.

Additionally, Wiltek does not include the term 'cannulation' in their intended use. However, this is a common practice among biliary endoscopists and a term found in the labeling accompanying other competitive papillotomes, such as the Wilson Cook papillotome supplied in Appendix C.

Although there may be minor differences in the manufacture and packaging of the Bard papillotomes, they are considered substantially equivalent to the Wiltek papillotomes. Any difference between the products raises no issue of safety or effectiveness based upon bow orientation, joint integrity, radiopacity, electrical and biocompatibility testing.



SEP 10 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Marion Gordon  
Regulatory Affairs Coordinator  
C. R. Bard, Inc.  
129 Concord Road, Bldg. 3  
P.O. Box 7031  
Billerica, MA 01821-7031Re: K982557  
Bard® ProForma™ and Apollo™ Pre-Curved Papillotomes  
Dated: July 21, 1998  
Received: July 22, 1998  
Regulatory Class: II  
21 CFR 876.4300/Procode: 78 KNS

Dear Mr. Gordon:

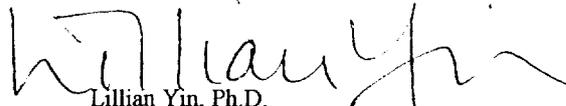
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): TBD

Device Name: Bard® ProForma™ and Apollo<sup>3</sup>™ Papillotomes

Indications For Use: Bard papillotomes are designed and recommended for transendoscopic cannulation and sphincterotomy of the Papilla of Vater and/or Sphincter of Oddi.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Szymon  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K982557

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use           

(Optional Format 1-2-96)