

**K982557 BARD PROFORMA AND APOLLO PRE-CURVED  
PAPILLOTOMES**Sep 10, 1998  
50 days to decisionK982557 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k982557/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS) |
| Date received         | Jul 22, 1998  |
| Decision date         | Sep 10, 1998  |
| Days to decision      | 50 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Bard Interventional Products Div.</b> |
| Location       | Billerica, MA, US                        |
| Contact        | MARION GORDON                            |
| 510(k) history | 2 submissions · 2 cleared · 1996-1998    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982557/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated July 1, 2026