

K963484 BARD HIGH FLOW PAPILOTOMENov 19, 1996
77 days to decisionK963484 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k963484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Sep 3, 1996
Decision date	Nov 19, 1996
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bard Interventional Products Div.
Location	Billerica, MA, US
Contact	BETH A ROCHETTE, R.A.C.
510(k) history	2 submissions · 2 cleared · 1996-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963484/> Data sourced from FDA 510(k) public records (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. - Generated July 1, 2026