

**K863354 BIO-GUARD AB COATED CATHETER**Nov 4, 1986  
67 days to decisionK863354 · Product code: **KOD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k863354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Aug 29, 1986
Decision date	Nov 4, 1986
Days to decision	67 days
Third-party review	No

**APPLICANT**

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Company	<b>Cook Urological, Inc.</b>
Location	Spencer, IN, US
Contact	FREDERICK D ROEMER
510(k) history	104 submissions · 102 cleared · 1986-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863354/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026