

**K173414 Advance Biliary Balloon Catheter**Jun 22, 2018  
233 days to decisionK173414 · Product code: **GCA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k173414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection (GCA)
Date received	Nov 1, 2017
Decision date	Jun 22, 2018
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Colin Jacob
510(k) history	175 submissions · 153 cleared · 2006-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173414/> 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 May 30, 2026