

K910917 CATHLAB SILICONE BILIARY BALLOON CATHETERAug 2, 1991
150 days to decisionK910917 · Product code: **GCA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k910917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection (GCA)
Date received	Mar 5, 1991
Decision date	Aug 2, 1991
Days to decision	150 days
Third-party review	No

APPLICANT

Company	Cathlab Corp.
Location	Tustin, CA, US
Contact	DANIEL R LUCAS
510(k) history	8 submissions · 8 cleared · 1988-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910917/>, 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 2, 2026