

K980917 ALL SLICONE DRAINAGE, PENROSE DRAIN, CWV DRAIN, THORACIC DRAIN TUBES AND CWV RESERVOIRMay 27, 1998
77 days to decisionK980917 · Product code: **GCA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k980917/>**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 11, 1998
Decision date	May 27, 1998
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fortune Medical Instrument Corp.
Location	Taipei Hsien, TW
Contact	KAREN U SALINAS
510(k) history	6 submissions · 6 cleared · 1998-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980917/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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