

**K990867 RX HERCULINK 14 BILIARY STENT SYSTEM, MODEL
1005126-18,1005128-18,1005130-18,1005132-18,1005134-18,1005
136-18,1005138-18**

Sep 2, 1999
170 days to decision

K990867 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k990867/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 16, 1999
Decision date	Sep 2, 1999
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Cardiovascular Systems, Inc.
Location	Santa Clara, CA, US
Contact	SANDRA SUNDELL
510(k) history	103 submissions · 100 cleared · 1982-2002

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k990867/>; 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