

K000550 OTW MEGALINK SDS BILIARY STENT SYSTEMMar 17, 2000
28 days to decisionK000550 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k000550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 18, 2000
Decision date	Mar 17, 2000
Days to decision	28 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

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