

K900904 CANDELA DIRECTABLE BILIARY CATHETER SYSTEMMay 11, 1990
73 days to decisionK900904 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k900904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 27, 1990
Decision date	May 11, 1990
Days to decision	73 days
Third-party review	No

APPLICANT

Company	Candela Laser Corp.
Location	Wayland, MA, US
Contact	GEORGE CHO
510(k) history	43 submissions · 43 cleared · 1988-1996

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