

K912443 CANDELA INTRODUCER SHEATH SYSTEMAug 16, 1991
74 days to decisionK912443 · Product code: **FDE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k912443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscopy Kit (FDE)
Date received	Jun 3, 1991
Decision date	Aug 16, 1991
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

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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