FDA 510(k) Premarket Notification

K062805 MODIFICATION TO ENDO-EASE

CLEARED

Oct 13, 2006
24 days to decision

K062805 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k062805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Sep 19, 2006
Decision date	Oct 13, 2006
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spirus Medical, Inc.**
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	5 submissions · 5 cleared · 2005-2008