FDA 510(k) Premarket Notification

K120766 ENDOSCOPIC DIAGNOSTIC & TREATMENT SYSTEM (MODIFICATION)

CLEARED

Sep 11, 2012
182 days to decision

K120766 · Product code: **FAJ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k120766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Mar 13, 2012
Decision date	Sep 11, 2012
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Prosurg, Inc.**
Location	San Jose, CA, US
Contact	A. DESAI
510(k) history	16 submissions · 16 cleared · 2000-2016