FDA 510(k) Premarket Notification

CLEARED

K061646 LASERSCOPE GUIDED DELIVERY DEVICE (GDD) CYSTOURETHROSCOPE & ACCESSORIES

Jun 27, 2006
15 days to decision

K061646 · Product code: **FBO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k061646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystourethroscope (FBO)
Date received	Jun 12, 2006
Decision date	Jun 27, 2006
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Laserscope**
Location	Santa Clara, CA, US
Contact	PAUL HARDIMAN
510(k) history	60 submissions · 60 cleared · 1985-2006