FDA 510(k) Premarket Notification

K051905 UROPLASTY RIGID ENDOSCOPIC NEEDLE

CLEARED

Aug 29, 2005
46 days to decision

K051905 · Product code: **FBK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k051905/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jul 14, 2005
Decision date	Aug 29, 2005
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Uroplasty, Inc.**
Location	Minneapolis, MN, US
Contact	MICHAEL MORRELL
510(k) history	8 submissions · 8 cleared · 2005-2012