FDA 510(k) Premarket Notification

K053322 MODIFICATION TO: ROEI WORKING ELEMENT AND ROEI CUTTING LOOPS

CLEARED

Jan 6, 2006
37 days to decision

K053322 · Product code: **FAS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k053322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Nov 30, 2005
Decision date	Jan 6, 2006
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roei Medical Technologies, Ltd.**
Location	Washington, Dc, DC, US
Contact	JONATHAN S KAHN
510(k) history	2 submissions · 2 cleared · 2005-2006