

**K053322 MODIFICATION TO: ROEI WORKING ELEMENT AND
ROEI CUTTING LOOPS**Jan 6, 2006
37 days to decisionK053322 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026