

**K061541 KSEA BIPOLAR ELECTROTOME**Aug 21, 2006  
77 days to decisionK061541 · Product code: **FAS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k061541/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Jun 5, 2006
Decision date	Aug 21, 2006
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ksea</b>
Location	Culver City, CA, US
Contact	JAMES A LEE
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061541/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026