FDA 510(k) Premarket Notification

K061541 KSEA BIPOLAR ELECTROTOME

CLEARED

Aug 21, 2006
77 days to decision

K061541 · Product code: **FAS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k061541/

SUBMISSION DETAILS

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

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