FDA 510(k) Premarket Notification

K003439 VIVANT BREAST LESION LOCALIZATION DEVICE

CLEARED

Dec 15, 2000
39 days to decision

K003439 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k003439/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 6, 2000
Decision date	Dec 15, 2000
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vivant Medical, Inc.**
Location	Portola Valley, CA, US
Contact	GEORGE HERMANN
510(k) history	10 submissions · 10 cleared · 2000-2005