FDA 510(k) Premarket Notification

K013025 MODIFICATION TO FLOUROLAB PLUS

CLEARED

Oct 3, 2001
23 days to decision

K013025 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k013025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 10, 2001
Decision date	Oct 3, 2001
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Z-Kat, Inc.**
Location	Hollywood, FL, US
Contact	WILLIAM F TAPIA
510(k) history	5 submissions · 5 cleared · 1999-2003