FDA 510(k) Premarket Notification

K013489 KP + LFM

CLEARED

Nov 29, 2001
38 days to decision

K013489 · Product code: **BZH** · Anesthesiology
Source: https://www.510kdatabase.net/k013489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	Oct 22, 2001
Decision date	Nov 29, 2001
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pds Healthcare Products, Inc.**
Location	Louisville, CO, US
Contact	JIM LEWIS
510(k) history	2 submissions · 2 cleared · 2001-2001