FDA 510(k) Premarket Notification

K953675 ALTADYNE

CLEARED

Sep 28, 1995
52 days to decision

K953675 · Product code: **FNM** · General Hospital
Source: https://www.510kdatabase.net/k953675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mattress, Air Flotation, Alternating Pressure (FNM)
Date received	Aug 7, 1995
Decision date	Sep 28, 1995
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lumex, Inc.**
Location	Bay Shore, NY, US
Contact	JAMES TERRACCIANO
510(k) history	8 submissions · 8 cleared · 1990-1997