FDA 510(k) Premarket Notification

K830778 MONITORING KIT AMK-1

CLEARED

Oct 14, 1983
217 days to decision

K830778 · Product code: **FLS** · Anesthesiology
Source: https://www.510kdatabase.net/k830778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Apnea, Facility Use (FLS)
Date received	Mar 11, 1983
Decision date	Oct 14, 1983
Days to decision	217 days
Third-party review	No

APPLICANT

Company	**Alternative Design Systems, Inc.**
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1983-1988