FDA 510(k) Premarket Notification

K831638 SINGLE BED ARRHYTHMIA MONITOR AM500

CLEARED

Nov 14, 1983
175 days to decision

K831638 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k831638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	May 23, 1983
Decision date	Nov 14, 1983
Days to decision	175 days
Third-party review	No

APPLICANT

Company	**Lifeline Systems, Inc.**
Location	Walker, MI, US
510(k) history	4 submissions · 4 cleared · 1983-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k831638/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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