FDA 510(k) Premarket Notification

K862463 LIFESCOPE 8, OEC-8120 PORTABLE PATIENT MONITOR REC

CLEARED

Dec 5, 1986
158 days to decision

K862463 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k862463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jun 30, 1986
Decision date	Dec 5, 1986
Days to decision	158 days
Third-party review	No

APPLICANT

Company	**Nihon Kohden America, Inc.**
Location	Foothill Ranch, CA, US
Contact	DENNIS JAVENS
510(k) history	166 submissions · 163 cleared · 1979-2012