FDA 510(k) Premarket Notification

K841501 LIFESCOPE 6 OEC-6102

CLEARED

Aug 28, 1984
140 days to decision

K841501 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k841501/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Apr 10, 1984
Decision date	Aug 28, 1984
Days to decision	140 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k841501/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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