FDA 510(k) Premarket Notification

K901034 MODELS WEP-8410A AND WEP-8420A TELEMETRY CENTRAL

CLEARED

Apr 19, 1990
44 days to decision

K901034 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k901034/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Mar 6, 1990
Decision date	Apr 19, 1990
Days to decision	44 days
Third-party review	No

APPLICANT

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