FDA 510(k) Premarket Notification

K920743 DUAL LEAD (ECG1 & ECG2) ARRHYTHMIA ANALYSIS

CLEARED

Sep 3, 1992
202 days to decision

K920743 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k920743/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Feb 14, 1992
Decision date	Sep 3, 1992
Days to decision	202 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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