FDA 510(k) Premarket Notification

CLEARED

K072217 ECG-1250A SERIES CARDIOFAX S AND ECG-1350A SERIES CARDIOFAX M

Aug 30, 2007
21 days to decision

K072217 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k072217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Aug 9, 2007
Decision date	Aug 30, 2007
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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