

K042827 CARDIOFAX CE, MODEL PEA-1110KJan 6, 2005
86 days to decisionK042827 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k042827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Oct 12, 2004
Decision date	Jan 6, 2005
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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