

K173226 CardiMax ElectrocardiographApr 16, 2018
195 days to decisionK173226 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k173226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Oct 3, 2017
Decision date	Apr 16, 2018
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fukuda Denshi USA, Inc.
Location	Mchenry, IL, US
Contact	Doug Blakely
510(k) history	68 submissions · 68 cleared · 1984-2018

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