

K191692 KardioScreenJan 10, 2020
199 days to decisionK191692 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k191692/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jun 25, 2019
Decision date	Jan 10, 2020
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imedrix Inc. (Formerly Piitech Inc.)
Location	Milpitas, CA, US
Contact	Srikanth Jadcherla
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191692/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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