FDA 510(k) Premarket Notification

K191692 KardioScreen

CLEARED

Jan 10, 2020
199 days to decision

K191692 · 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