

K182571 CardioFlux with Faraday Analytical CloudMar 15, 2019
178 days to decisionK182571 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k182571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Sep 18, 2018
Decision date	Mar 15, 2019
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genetesis, Inc.
Location	Mason, OH, US
Contact	Robert Sokolowski
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182571/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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