FDA 510(k) Premarket Notification

K180234 physiQ Heart Rhythm Module

CLEARED

Aug 10, 2018
193 days to decision

K180234 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k180234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jan 29, 2018
Decision date	Aug 10, 2018
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Physiq, Inc.**
Location	Naperville, IL, US
Contact	George Allen Hides
510(k) history	3 submissions · 3 cleared · 2018-2020

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k180234/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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