

K181352 Loop SystemMar 29, 2019
311 days to decisionK181352 · Product code: **DQA** · Cardiovascular
Source: <https://www.510kdatabase.net/k181352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 22, 2018
Decision date	Mar 29, 2019
Days to decision	311 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spry Health, Inc.
Location	Palo Alto, CA, US
Contact	Elad Ferber
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Coombs Medical Device Consulting, Inc.
Contact	Craig Coombs

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181352/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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