

K213255 CipherOx CRI TabletJun 17, 2022
260 days to decisionK213255 · Product code: **PPW** · Cardiovascular
Source: <https://www.510kdatabase.net/k213255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Cardiovascular Status Indicator (PPW)
Date received	Sep 30, 2021
Decision date	Jun 17, 2022
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Flashback Technologies, Inc.
Location	Boulder, CO, US
Contact	John Jedziniak
510(k) history	3 submissions · 2 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

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