

K202359 Zio MonitorMay 21, 2021
275 days to decisionK202359 · Product code: **DSH** · CardiovascularSource: <https://www.510kdatabase.net/k202359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Aug 19, 2020
Decision date	May 21, 2021
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	iRhythm Technologies, Inc.
Location	San Francisco, CA, US
Contact	Rich Laguna
510(k) history	17 submissions · 17 cleared · 2008-2025

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