

K143513 ZIO SR ECG Monitoring ServiceJun 19, 2015
190 days to decisionK143513 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k143513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Dec 11, 2014
Decision date	Jun 19, 2015
Days to decision	190 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143513/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026