

K190593 Zio XT ECG Monitoring System, Zio AT ECG Monitoring SystemAug 23, 2019
169 days to decisionK190593 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k190593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 7, 2019
Decision date	Aug 23, 2019
Days to decision	169 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	Gabrielle Logan
510(k) history	18 submissions · 18 cleared · 2008-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190593/> 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 28, 2026