FDA 510(k) Premarket Notification

CLEARED

K190593 Zio XT ECG Monitoring System, Zio AT ECG Monitoring System

Aug 23, 2019
169 days to decision

K190593 · 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