FDA 510(k) Premarket Notification

K163512 Zio AT ECG Monitoring System

CLEARED

Jun 2, 2017
169 days to decision

K163512 · Product code: **QYX** · Cardiovascular
Source: https://www.510kdatabase.net/k163512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Dec 15, 2016
Decision date	Jun 2, 2017
Days to decision	169 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