

K200833 RX-1 Rhythm Express Remote Cardiac Monitoring System

Sep 2, 2020
156 days to decisionK200833 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k200833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Mar 30, 2020
Decision date	Sep 2, 2020
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vivaquant, Inc.
Location	St. Paul, MN, US
Contact	Brian Brockway
510(k) history	3 submissions · 3 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200833/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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