FDA 510(k) Premarket Notification

CLEARED

K183704 RX-1 Rhythm Express Remote Cardiac Monitoring System

Feb 16, 2019
47 days to decision

K183704 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k183704/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Dec 31, 2018
Decision date	Feb 16, 2019
Days to decision	47 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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