FDA 510(k) Premarket Notification

K182456 Study Watch

CLEARED

Jan 17, 2019
132 days to decision

K182456 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k182456/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 7, 2018
Decision date	Jan 17, 2019
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Verily Life Sciences, LLC**
Location	South San Francisco, CA, US
Contact	Shilpa Mydur
510(k) history	4 submissions · 4 cleared · 2019-2024