FDA 510(k) Premarket Notification

CLEARED

K192415 Study Watch with Irregular Pulse Monitor

Jan 17, 2020
135 days to decision

K192415 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k192415/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 4, 2019
Decision date	Jan 17, 2020
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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