FDA 510(k) Premarket Notification

K201208 Halo AF Detection System

CLEARED

Sep 23, 2020
141 days to decision

K201208 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k201208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 5, 2020
Decision date	Sep 23, 2020
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Livmor**
Location	Irvine, CA, US
Contact	Ken Persen
510(k) history	1 submissions · 1 cleared · 2020-2020