FDA 510(k) Premarket Notification

CLEARED

K151269 ECG Mini System Continuous ECG Monitor and Arrhythmia Detector

Jan 15, 2016
247 days to decision

K151269 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k151269/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	May 13, 2015
Decision date	Jan 15, 2016
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifewatch Technologies , Ltd.**
Location	Rehovot, IL
Contact	Asher Kassel
510(k) history	4 submissions · 4 cleared · 2014-2016