FDA 510(k) Premarket Notification

K181658 MobileECG 2 BT

CLEARED

Mar 26, 2019
274 days to decision

K181658 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k181658/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jun 25, 2018
Decision date	Mar 26, 2019
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Memtec Corporation**
Location	Salem, NH, US
Contact	Dennis Garboski
510(k) history	1 submissions · 1 cleared · 2019-2019