FDA 510(k) Premarket Notification

K183370 PeraMobile and PeraWatch

CLEARED

Sep 11, 2019
281 days to decision

K183370 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k183370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 4, 2018
Decision date	Sep 11, 2019
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Perahealth, Inc.**
Location	Charlotte, NC, US
Contact	Brad Coleman
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Biologics Consulting Group**
Contact	Donna-Bea Tillman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov