FDA 510(k) Premarket Notification

K172959 PeraServer and PeraTrend

CLEARED

May 1, 2018
217 days to decision

K172959 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k172959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 26, 2017
Decision date	May 1, 2018
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

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

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