FDA 510(k) Premarket Notification

CLEARED

K201746 Tempus Pro Patient Monitor

Sep 18, 2020
84 days to decision

K201746 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k201746/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 26, 2020
Decision date	Sep 18, 2020
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Remote Diagnostic Technologies Limited**
Location	Basingstoke, GB
Contact	Timothy Bubb
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Philips North America, LLC**
Contact	Neha Hardiya

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