FDA 510(k) Premarket Notification

K173768 Tempus Pro Patient Monitor

CLEARED

Jan 10, 2018
30 days to decision

K173768 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k173768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 11, 2017
Decision date	Jan 10, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Remote Diagnostic Technologies , Ltd.**
Location	Basingstoke, Hampshire, GB
Contact	James Hamlyn
510(k) history	11 submissions · 11 cleared · 2001-2018