FDA 510(k) Premarket Notification

K170567 Tempus Pro Patient Monitor

CLEARED

Jul 6, 2017
129 days to decision

K170567 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k170567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 27, 2017
Decision date	Jul 6, 2017
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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