FDA 510(k) Premarket Notification

K101264 TEMPUS IC PROFESSIONAL PATIENT MONITOR

CLEARED

May 11, 2010
6 days to decision

K101264 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k101264/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	May 5, 2010
Decision date	May 11, 2010
Days to decision	6 days
Third-party review	Yes
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