FDA 510(k) Premarket Notification

K101127 PATIENT MONITOR, MODEL PM50

CLEARED

Jun 11, 2010
50 days to decision

K101127 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k101127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 22, 2010
Decision date	Jun 11, 2010
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Contec Medical System Co., Ltd.**
Location	Zhong Shan, Shanghai, CN
Contact	Diana Hong
510(k) history	12 submissions · 12 cleared · 2008-2019