FDA 510(k) Premarket Notification

K162234 Truscope Ultra Patient Monitor

CLEARED

Jan 4, 2017
148 days to decision

K162234 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k162234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Aug 9, 2016
Decision date	Jan 4, 2017
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Guangdong Biolight Meditech Co., Ltd.**
Location	Shanghai, CN
Contact	Jing Liang
510(k) history	21 submissions · 21 cleared · 2008-2019