FDA 510(k) Premarket Notification

K181919 Patient Monitor

CLEARED

Apr 5, 2019
261 days to decision

K181919 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k181919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 18, 2018
Decision date	Apr 5, 2019
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov