FDA 510(k) Premarket Notification

K172965 Handheld VitalSigns Monitoring System

CLEARED

Dec 17, 2018
447 days to decision

K172965 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k172965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 26, 2017
Decision date	Dec 17, 2018
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visiomed Technology Co.,Ltd**
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Contact	Chen XiaoFeng
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Filed Fu

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