FDA 510(k) Premarket Notification

CLEARED

K140339 VITAL SYNC INFORMATICS MANAGER & VIRTUAL PATIENT MONITORING PLATFORM

Apr 10, 2014
59 days to decision

K140339 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k140339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Feb 10, 2014
Decision date	Apr 10, 2014
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien**
Location	North Haven, CT, US
Contact	BRIANNA REYNOLDS
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...