

K130796 VITAL SYNC INFORMATICS MANAGER & VIRTUAL PATIENT MONITORING PLATFORMMay 9, 2013
48 days to decisionK130796 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k130796/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Mar 22, 2013 |
| Decision date | May 9, 2013 |
| Days to decision | 48 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien |
| Location | North Haven, CT, US |
| Contact | KELSEY LEE |
| 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...