

K123002 VITAL SYNC SYSTEM

Feb 27, 2013
153 days to decision

K123002 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k123002/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 27, 2012
Decision date	Feb 27, 2013
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, Formerly Nellcor Puritan Bennett, Inc.
Location	Boulder, CO, US
Contact	KELSEY LEE
510(k) history	5 submissions · 5 cleared · 2008-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k123002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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