

K130320 BEDSIDE RESPIRATORY PATIENT MONITORING SYSTEM, BEDSIDE RESPIRATORY PATIENT MONITORING SYSTEM WITH RESPIRATION RATE SOFTWFeb 4, 2014
361 days to decisionK130320 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k130320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Feb 8, 2013
Decision date	Feb 4, 2014
Days to decision	361 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	ELIZABETH MALO
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...