

K142335 RapidVac Smoke Evacuator SystemJan 14, 2015
146 days to decisionK142335 · Product code: **FYD** · General Hospital
Source: <https://www.510kdatabase.net/k142335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Exhaust, Surgical (FYD)
Date received	Aug 21, 2014
Decision date	Jan 14, 2015
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	JOSE MARQUEZ
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...

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Device record: <https://www.510kdatabase.net/k142335/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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