

K173603 Monarch Airway Clearance SystemOct 24, 2018
337 days to decisionK173603 · Product code: **BYI** · Anesthesiology
Source: <https://www.510kdatabase.net/k173603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Nov 21, 2017
Decision date	Oct 24, 2018
Days to decision	337 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hill-Rom Holdings, Inc.
Location	Singapore, SG
Contact	Joseph Braido
Website	http://www.hill-rom.com
510(k) history	1 submissions · 1 cleared · 2018-2018

Hill-Rom Holdings, Inc. is a global medical device manufacturer with a manufacturing facility in Singapore. The company advances connected care solutions across hospital, surgical, and home healthcare settings. Hill-Rom has received FDA 510(k) clearance from total submission. The company's regulatory focus centers on Anesthesiology devices. The Monarch Airway Clearance System represents the company's cleared innovation in this category, with clearance granted in 2018. Hill-Rom's regulatory activity is historical. No new FDA 510(k) clearances have been submitted in more th...

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Device record: <https://www.510kdatabase.net/k173603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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