

K220565 Hudson RCI Triflo II Incentive Deep Breathing ExerciserOct 25, 2022
239 days to decisionK220565 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k220565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Feb 28, 2022
Decision date	Oct 25, 2022
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Nicole Schaffer
510(k) history	238 submissions · 234 cleared · 1977-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Joy Gutermuth

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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