

K213068 Medline Smoke Evacuation ShroudJan 3, 2022
102 days to decisionK213068 · Product code: **FYD** · General Hospital
Source: <https://www.510kdatabase.net/k213068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Exhaust, Surgical (FYD)
Date received	Sep 23, 2021
Decision date	Jan 3, 2022
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026