

K043017 PREVENTION BREATHABLE, IMPERVIOUS SURGICAL GOWNSMar 8, 2005
126 days to decisionK043017 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k043017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 2, 2004
Decision date	Mar 8, 2005
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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