

K160471 Medline Non-Surgical Isolation Gown-Jan 31, 2017
347 days to decisionK160471 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k160471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Feb 19, 2016
Decision date	Jan 31, 2017
Days to decision	347 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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