

K111535 EMM SURGICAL GOWN - SPUNLACE WITH PE LAYERAug 26, 2011
85 days to decisionK111535 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k111535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 2, 2011
Decision date	Aug 26, 2011
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exact Medical Manufacturing, Inc.
Location	Buffalo, NY, US
Contact	ROBERT O DEAN
510(k) history	7 submissions · 7 cleared · 2010-2013

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