

**K120045 EMM HIGH PERFORMANCE SURGICAL GOWN WITH  
AAMI LIQUID BARRIER LEVEL IV**Jun 12, 2012  
158 days to decisionK120045 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k120045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jan 6, 2012
Decision date	Jun 12, 2012
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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