

**K101593 EMM SURGICAL GOWN-SMS WITH PE LAYER,
MODEL 18-501 L, 18-501-XL, 18-501 XXL, 18-501-XXLXL**Sep 3, 2010
87 days to decisionK101593 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k101593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 8, 2010
Decision date	Sep 3, 2010
Days to decision	87 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101593/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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