

**K091097 PROMEDICAL SURGICAL GOWN, MODELS 18-301,  
18-401 AND 18-501**May 27, 2009  
41 days to decisionK091097 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k091097/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gown, Surgical (FYA)
Date received	Apr 16, 2009
Decision date	May 27, 2009
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Promedical Products Co., Ltd.</b>
Location	Starkville, MS, US
Contact	DAVID POWER
510(k) history	6 submissions · 6 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091097/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 23, 2026