

**K042111 PROMEDICAL SURGICAL GOWNS**Dec 10, 2004  
127 days to decisionK042111 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k042111/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 5, 2004
Decision date	Dec 10, 2004
Days to decision	127 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	BOYD HARRIS
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/k042111/> 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