

**K041540 COMBOSAFE (EUROPE) AND PROMAX (US)  
SURGICAL GOWNS**May 5, 2005  
331 days to decisionK041540 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k041540/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gown, Surgical (FYA)               |
| Date received         | Jun 8, 2004                        |
| Decision date         | May 5, 2005                        |
| Days to decision      | 331 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Standard Textile Co., Inc.</b>   |
| Location       | Cincinnati, OH, US  |
| Contact        | BRADLEY J BUSHMAN   |
| Website        | <a href="http://www.standardtextile.com">http://www.standardtextile.com</a> |
| 510(k) history | 23 submissions · 23 cleared · 1986-2024                                     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041540/> 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 1, 2026