

**K952116 COVER GOWN**Sep 5, 1995  
123 days to decisionK952116 · Product code: **FYC** · General HospitalSource: <https://www.510kdatabase.net/k952116/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gown, Isolation, Surgical (FYC)    |
| Date received         | May 5, 1995                        |
| Decision date         | Sep 5, 1995                        |
| Days to decision      | 123 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|--|
| Company        | <b>American Threshold Industries, Inc.</b> |
| Location       | Walker, MI, US                             |
| Contact        | GREGORY B SCOTT                            |
| 510(k) history | 20 submissions · 20 cleared · 1980-1997    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952116/> 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 30, 2026