

**K012240 MERTEX-PLUS O.R./SURGEONS GOWN, NONSTERILE**Oct 15, 2001  
90 days to decisionK012240 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k012240/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gown, Surgical (FYA)               |
| Date received         | Jul 17, 2001                       |
| Decision date         | Oct 15, 2001                       |
| Days to decision      | 90 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mercan AB</b>                      |
| Location       | Austin, TX, US                        |
| Contact        | JEFFREY O STULL                       |
| 510(k) history | 2 submissions · 2 cleared · 2001-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012240/> 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 July 3, 2026