

K953251 MERTEX-PLUS O.R./SURGEONS GOWNSep 5, 1995
55 days to decisionK953251 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k953251/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Surgical (FYA) |
| Date received | Jul 12, 1995 |
| Decision date | Sep 5, 1995 |
| Days to decision | 55 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mercana Industries , Ltd. |
| Location | Richmond Hill, CA |
| Contact | LEN P KLEINE |
| 510(k) history | 1 submissions · 1 cleared · 1995-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953251/> Data sourced from FDA 510(k) public records (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. - Generated July 6, 2026