

K061308 TRIMAX, MODEL 9515N, BREATHABLE SURGICAL GOWN, MODELS 3247AN AND 9015N AND OPTIMA OR SURGICAL GOWN, MODEL 9506NJun 5, 2006
26 days to decisionK061308 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k061308/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Gown, Surgical (FYA) |
| Date received | May 10, 2006 |
| Decision date | Jun 5, 2006 |
| Days to decision | 26 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cardinal Health 200, Inc. |
| Location | Waukegan, IL, US |
| Contact | LAVENIA FORD |
| 510(k) history | 3 submissions · 3 cleared · 2006-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061308/>; 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 June 3, 2026