

K944138 INTERWOVEN OPTIGUARD REUSABLE GOWN MATERIALDec 20, 1994
118 days to decisionK944138 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k944138/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Surgical (FYA) |
| Date received | Aug 24, 1994 |
| Decision date | Dec 20, 1994 |
| Days to decision | 118 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Healthcare Corp |
| Location | Mchenry, IL, US |
| Contact | ELIZABETH C DUDLEY |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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