

**K921613 STERILIZER, SURG INSTR/DRESSING
#6530-01-306-9510**

Jan 29, 1993
298 days to decision

K921613 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k921613/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sterilizer, Steam (FLE) |
| Date received | Apr 6, 1992 |
| Decision date | Jan 29, 1993 |
| Days to decision | 298 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dept. of the Army |
| Location | Frederick, MD, US |
| Contact | GREGORY P BEREZUK |
| 510(k) history | 5 submissions · 5 cleared · 1989-2003 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k921613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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