

K821591 STEAM STERILIZATION EQUIPMENTJun 22, 1982
21 days to decisionK821591 · Product code: **FLE** · General HospitalSource: <https://www.510kdatabase.net/k821591/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sterilizer, Steam (FLE) |
| Date received | Jun 1, 1982 |
| Decision date | Jun 22, 1982 |
| Days to decision | 21 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Getinge International, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 4 submissions · 4 cleared · 1982-1994 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821591/> 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