

K120441 GETINGE 700HC-E SERIES STEAM STERILIZERMay 31, 2012
108 days to decisionK120441 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k120441/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sterilizer, Steam (FLE) |
| Date received | Feb 13, 2012 |
| Decision date | May 31, 2012 |
| Days to decision | 108 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Getinge Sourcing, LLC |
| Location | Rochester, NY, US |
| Contact | BARB SMITH |
| 510(k) history | 7 submissions · 7 cleared · 2007-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120441/> 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 2, 2026