

**K140487 VIS-U-ALL LOW TEMPERATURE STERILIZATION
POUCH/TUBING**Jul 22, 2014
145 days to decisionK140487 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k140487/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wrap, Sterilization (FRG) |
| Date received | Feb 27, 2014 |
| Decision date | Jul 22, 2014 |
| Days to decision | 145 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | STERIS Corporation |
| Location | Mentor, OH, US |
| Contact | TONY PIOTRKOWSKI |
| 510(k) history | 204 submissions · 202 cleared · 1997-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140487/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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