

K170427 Anprolene SteriTestOct 31, 2017
260 days to decisionK170427 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k170427/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Feb 13, 2017 |
| Decision date | Oct 31, 2017 |
| Days to decision | 260 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Andersen Sterilizers, Inc. |
| Location | Haw River, NC, US |
| Contact | William K. Andersen |
| 510(k) history | 19 submissions · 19 cleared · 2015-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170427/> 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 May 27, 2026