

K213296 Anprolene SteriTest RRBIApr 12, 2022
193 days to decisionK213296 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k213296/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Oct 1, 2021 |
| Decision date | Apr 12, 2022 |
| Days to decision | 193 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | 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/k213296/> 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