

**K981497 STERITEC DISPOSABLE BIOLOGICAL TEST PACK-EO
GAS**

Oct 29, 1998
185 days to decision

K981497 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k981497/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Apr 27, 1998 |
| Decision date | Oct 29, 1998 |
| Days to decision | 185 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Steritec Products Mfg Co, Inc. |
| Location | Castle Rock, CO, US |
| Contact | TOM ROLL |
| 510(k) history | 22 submissions · 22 cleared · 1996-2020 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k981497/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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