

K173488 CELERITY 20 HP Challenge PackMar 1, 2018
108 days to decisionK173488 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k173488/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Nov 13, 2017 |
| Decision date | Mar 1, 2018 |
| Days to decision | 108 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173488/> 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 31, 2026