

K203177 Sterisystem Dry-Base Instrument TrayJan 2, 2022
433 days to decisionK203177 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k203177/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT) |
| Date received | Oct 26, 2020 |
| Decision date | Jan 2, 2022 |
| Days to decision | 433 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | O&M Halyard, Inc. |
| Location | Alpharetta, GA, US |
| Contact | Steven Dowdley |
| 510(k) history | 23 submissions · 23 cleared · 2019-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203177/> 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 13, 2026