

K222272 truFreeze Console, PN CC301Aug 18, 2022
20 days to decisionK222272 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k222272/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Unit, Cryosurgical, Accessories (GEH) |
| Date received | Jul 29, 2022 |
| Decision date | Aug 18, 2022 |
| Days to decision | 20 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Aire PV Passive Venting Catheter, PN CO840703; 16 Fr CDT 5 Pack, PN 2000181; 20Fr CDT 5 Pack, PN ACCCC3CDT05; Active Venting Spray Kit, 20 Fr CDT, PN 2000177; Active Venting Spray Kit 16 Fr CDT, PN 20000516; Rapid AV Catheter 5 Pack, PN 2000184 |

APPLICANT

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

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