

K223369 truFreeze Console, PN CC301Dec 2, 2022
28 days to decisionK223369 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k223369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Nov 4, 2022
Decision date	Dec 2, 2022
Days to decision	28 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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