

**K202461 ThermaCor 1200 Disposable Sets for the ThermaCor
1200 Rapid Thermal Infusion System**Aug 12, 2022
715 days to decisionK202461 · Product code: **LGZ** · General Hospital
Source: <https://www.510kdatabase.net/k202461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Thermal, Infusion Fluid (LGZ)
Date received	Aug 27, 2020
Decision date	Aug 12, 2022
Days to decision	715 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smisson-Carlledge Biomedical, LLC
Location	Alpharetta, GA, US
Contact	Calder Clay III
510(k) history	2 submissions · 2 cleared · 2006-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Resources Group, Inc.
Contact	Julie Stephens

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202461/> 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 26, 2026