

**K213191 S-Line**May 24, 2022  
237 days to decisionK213191 · Product code: **LGZ** · General Hospital  
Source: <https://www.510kdatabase.net/k213191/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Thermal, Infusion Fluid (LGZ)
Date received	Sep 29, 2021
Decision date	May 24, 2022
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Barkey GmbH &amp; Co. KG</b>
Location	Leopoldshoehe, DE
Contact	Thomas Barkey
510(k) history	2 submissions · 2 cleared · 2007-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedic Consulting, LLC</b>
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213191/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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