FDA 510(k) Premarket Notification

# K213191 S-Line

**CLEARED**

May 24, 2022
237 days to decision

K213191 · Product code: **LGZ** · General Hospital
Source: https://www.510kdatabase.net/k213191/

## SUBMISSION DETAILS

| | |
|---|---|
| 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

| | |
|---|---|
| Company | **Barkey GmbH & Co. KG** |
| Location | Leopoldshoehe, DE |
| Contact | Thomas Barkey |
| 510(k) history | 2 submissions · 2 cleared · 2007-2022 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **ProMedic Consulting, LLC** |
| Contact | Paul Dryden |

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