

K211618 Fluido Compact Blood and Fluid Warming SystemJun 5, 2023
740 days to decisionK211618 · Product code: **LGZ** · General Hospital
Source: <https://www.510kdatabase.net/k211618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Thermal, Infusion Fluid (LGZ)
Date received	May 26, 2021
Decision date	Jun 5, 2023
Days to decision	740 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Surgical Company International B.V.
Location	Beeldschemweg 6g, NL
Contact	Inette Nieveen
510(k) history	3 submissions · 3 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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