

K191425 Hydro-Temp Neonatal Skin Temperature Probe CoverJan 21, 2020
237 days to decisionK191425 · Product code: **FMT** · General Hospital
Source: <https://www.510kdatabase.net/k191425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	May 29, 2019
Decision date	Jan 21, 2020
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Deroyal Industries, Inc.
Location	Mchenry, IL, US
Contact	Sarah Bennett
510(k) history	91 submissions · 88 cleared · 1984-2025

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