

**K200319 HYDRO-TEMP Neonatal Skin Surface Temperature Sensor, HYDRO-TEMP Neonatal Skin Surface Temperature Sensor with Interface Cable**Apr 2, 2020  
55 days to decisionK200319 · Product code: **FMT** · General Hospital  
Source: <https://www.510kdatabase.net/k200319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Feb 7, 2020
Decision date	Apr 2, 2020
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200319/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026