

**K011059 INFARED EAR THERMOMETER, MODEL TH8 SERIES**Sep 17, 2001  
164 days to decisionK011059 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k011059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 6, 2001
Decision date	Sep 17, 2001
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radiant Innovation, Inc.</b>
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	15 submissions · 15 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011059/> 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 June 20, 2026