

K163601 RII Smart IR ThermometerDec 6, 2018
715 days to decisionK163601 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k163601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Dec 21, 2016
Decision date	Dec 6, 2018
Days to decision	715 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Radiant Innovation, Inc.
Location	Great Neck, NY, US
Contact	Monica Chung
510(k) history	15 submissions · 15 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163601/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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