

**K173194 Temperature Probe**Oct 10, 2018  
373 days to decisionK173194 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k173194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Oct 2, 2017
Decision date	Oct 10, 2018
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orantech, Inc.</b>
Location	Shenzhen, CN
Contact	Hsin Xiong
510(k) history	5 submissions · 5 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Chonconn Medical Device Consulting Co., Ltd.</b>
Contact	Kevin Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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