

**K191004 Advocate Non-Contact Infrared Thermometer**Sep 5, 2019  
142 days to decisionK191004 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k191004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 16, 2019
Decision date	Sep 5, 2019
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Broadmaster Biotech, Corp.</b>
Location	Taoyuan City, TW
Contact	Jen Ke-Min
510(k) history	2 submissions · 2 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Chinese-European Industrial Research Society</b>
Contact	Jen Ke-Min

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191004/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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