

K180355 Advocate Non-Contact Infrared ThermometerJan 10, 2019
336 days to decisionK180355 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k180355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 8, 2018
Decision date	Jan 10, 2019
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Chinese-European Industrial Research Society
Contact	Ke-Min Jen

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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