

K201977 TempTraqDec 3, 2020
140 days to decisionK201977 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k201977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jul 16, 2020
Decision date	Dec 3, 2020
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Blue Spark Technologies, Inc.
Location	Westlake, OH, US
Contact	John Gannon
510(k) history	2 submissions · 2 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	MethodSense, Inc.
Contact	Rita King

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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