

K191978 Fever GardeDec 18, 2020
513 days to decisionK191978 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k191978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jul 24, 2019
Decision date	Dec 18, 2020
Days to decision	513 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hubdic Co., Ltd.
Location	Bonita Springs, FL, US
Contact	Shin Jae-Ho
510(k) history	6 submissions · 6 cleared · 2003-2020

REGULATORY CONSULTANT

Consulting firm	Plusglobal
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191978/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026