FDA 510(k) Premarket Notification

K191978 Fever Garde

CLEARED

Dec 18, 2020
513 days to decision

K191978 · 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