

K181239 Infrared Forehead Thermometer, Infrared Ear/Forehead ThermometerOct 29, 2018
172 days to decisionK181239 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k181239/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received | May 10, 2018 |
| Decision date | Oct 29, 2018 |
| Days to decision | 172 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Joytech Healthcare Co. , Ltd. |
| Location | Hangzhou, CN |
| Contact | Ren Yunhua |
| Website | https://www.joytechhealthcare.com |
| 510(k) history | 22 submissions · 22 cleared · 2017-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181239/> 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 28, 2026