

K240333 Wearable Digital Thermometer (T31)Oct 30, 2024
268 days to decisionK240333 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k240333/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received | Feb 5, 2024 |
| Decision date | Oct 30, 2024 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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|----------------|--|
| Company | Guangdong Genial Technology Co., Ltd. |
| Location | Zhaoqing, CN |
| Contact | Jun Yu |
| 510(k) history | 5 submissions · 5 cleared · 2023-2024 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Constant Medical Technology Co., Ltd. |
| Contact | Klem Hou |

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/k240333/> 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 May 13, 2026