

K212346 Infrared Thermometer, Model: PG-IRT1612, PG-IRT1613, PG-IRT1615, PG-IRT1618May 5, 2022
281 days to decisionK212346 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k212346/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received | Jul 28, 2021 |
| Decision date | May 5, 2022 |
| Days to decision | 281 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Pango Medical Electronics Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Youjian Xie |
| 510(k) history | 3 submissions · 3 cleared · 2022-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------------|
| Consulting firm | Mid-Link Consulting Co, Ltd. |
| Contact | Diana Hong |

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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