

K212945 Sterile Disposable Temperature ProbeMar 1, 2022
167 days to decisionK212945 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k212945/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received | Sep 15, 2021 |
| Decision date | Mar 1, 2022 |
| Days to decision | 167 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--------------------------------------------|
| Company | Shenzhen Envisen Industry Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Ailsa Huang |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------------------------------|
| Consulting firm | Shenzhen Chonconn Medical Consulting Co., Ltd. |
| Contact | Kevin Wang |

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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