

**K191251 Infrared Thermometer**Oct 15, 2019  
159 days to decisionK191251 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k191251/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received         | May 9, 2019                              |
| Decision date         | Oct 15, 2019                             |
| Days to decision      | 159 days                                 |
| Third-party review    | No                                       |
| Combination product   | No                                       |
| PCCP authorized       | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Shenzhen Calibeur Industries Co., Ltd.</b> |
| Location       | Shenzhen, CN                                  |
| Contact        | Weibin He                                     |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019         |

**REGULATORY CONSULTANT**

---

|                 |   |
|-----------------|---|
| Consulting firm | <b>Chonconn Medical Device Consulting Co., Ltd.</b> |
| 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)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191251/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026