

K213084 Ear Thermometer, Model ET005, ET008, ET009Feb 25, 2022
155 days to decisionK213084 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k213084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 23, 2021
Decision date	Feb 25, 2022
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Berrcom Medical Device Co., Ltd.
Location	Guangzhou, CN
Contact	Zhigang Du
510(k) history	6 submissions · 6 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Yoyo Chen

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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