

**K203431 Disposable Ear Thermometer Probe Cover**Jul 28, 2021  
247 days to decisionK203431 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k203431/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Nov 23, 2020
Decision date	Jul 28, 2021
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Huaian Zhongxin Packing Material Co., Ltd.</b>
Location	Huaian, CN
Contact	Feng Zuo
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle 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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