

**K161211 Digital Thermometer**Aug 29, 2016  
123 days to decisionK161211 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k161211/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 28, 2016
Decision date	Aug 29, 2016
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocare Asia Corporation , Ltd.</b>
Location	Suzhou, CN
Contact	KE-MIN JEN
510(k) history	3 submissions · 3 cleared · 2014-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161211/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 2, 2026