

K112189 THERMO PAL INFRARED EAR THERMOMETERJan 13, 2012
168 days to decisionK112189 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k112189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jul 29, 2011
Decision date	Jan 13, 2012
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Digio2 International Co., Ltd.
Location	Flagstaff, AZ, US
Contact	JENNIFER REICH
510(k) history	3 submissions · 3 cleared · 2009-2014

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