

K160358 DT-100Feb 24, 2017
381 days to decisionK160358 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k160358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 9, 2016
Decision date	Feb 24, 2017
Days to decision	381 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mediana Co., Ltd.
Location	Flintville, TN, US
Contact	Min-hye Kim
510(k) history	10 submissions · 10 cleared · 2005-2020

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