

K161735 Non-contact Forehead ThermometerNov 17, 2016
147 days to decisionK161735 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k161735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jun 23, 2016
Decision date	Nov 17, 2016
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Dongdixin Technology Co., Ltd.
Location	Shanghai, CN
Contact	Siping Yuan
510(k) history	25 submissions · 25 cleared · 2005-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161735/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026