

K152640 Infrared Thermometer (FT-F11-BT, FT-F21-BT, FT-31-BT, FT-F41-BT)Mar 28, 2016
195 days to decisionK152640 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k152640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 15, 2015
Decision date	Mar 28, 2016
Days to decision	195 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fudakang Industries Co., Ltd.
Location	Shenzhen, Guangdong, CN
Contact	BOB YU
510(k) history	2 submissions · 2 cleared · 2010-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152640/>. 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 June 3, 2026