

K213100 FMT Reusable Temperature ProbesJul 18, 2023
662 days to decisionK213100 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k213100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 24, 2021
Decision date	Jul 18, 2023
Days to decision	662 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Metko Medikal VE Ttbbi Cihazlar D1s Ticaret Ltd. Sti
Location	Yenimahalle - Ankara, TR
Contact	Burcu Firat
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Arazy Group Consultants, Inc.
Contact	Ray Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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