FDA 510(k) Premarket Notification

K222057 THERMOCLICK

CLEARED

Dec 5, 2023
511 days to decision

K222057 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k222057/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jul 12, 2022
Decision date	Dec 5, 2023
Days to decision	511 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**T&R BIOFAB CO., Ltd.**
Location	Siheung-Si, KR
Contact	Woo-Soo Yun
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Lighten Bridge, LLC**
Contact	Edward Park

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