FDA 510(k) Premarket Notification

K221211 Infrared thermometer

CLEARED

Sep 27, 2022
153 days to decision

K221211 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k221211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 27, 2022
Decision date	Sep 27, 2022
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shenzhen Yolanda Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Baihua Han
510(k) history	3 submissions · 3 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.**
Contact	Reanny Wang

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