FDA 510(k) Premarket Notification

CLEARED

K203707 Infrared Forehead Thermometer, Model JZK-601, JZK-602, JZK-603

Mar 12, 2021
84 days to decision

K203707 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k203707/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Dec 18, 2020
Decision date	Mar 12, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Zhengkang Technology Co., Ltd.**
Location	Shenzhen City, CN
Contact	Huayong Yang
510(k) history	3 submissions · 3 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov