FDA 510(k) Premarket Notification

K230889 Digital Thermometer

CLEARED

Apr 3, 2024
369 days to decision

K230889 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k230889/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 31, 2023
Decision date	Apr 3, 2024
Days to decision	369 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Wenzhou Yosun Medical Technology Co.,Ltd**
Location	Wenzhou, CN
Contact	Lihao Yang
510(k) history	3 submissions · 3 cleared · 2020-2024

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