FDA 510(k) Premarket Notification

K232816 Electrocardiograph, model: ECG301

CLEARED

Jun 7, 2024
268 days to decision

K232816 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k232816/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Sep 13, 2023
Decision date	Jun 7, 2024
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen LE Medical Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Wuyaxiong .
510(k) history	1 submissions · 1 cleared · 2024-2024