CLEARED

K230834 CARDIPIA ECG / Model: CARDIPIA400H, CARDIPIA800H

Nov 21, 2023
239 days to decision

K230834 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k230834/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 27, 2023
Decision date	Nov 21, 2023
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Trismed Co., Ltd.**
Location	Daejeon, KR
Contact	Sul Ki Lee
510(k) history	1 submissions · 1 cleared · 2023-2023