

K223670 MESI mTablet ECG Diagnostic System, MESI mTablet ECGJul 28, 2023
233 days to decisionK223670 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k223670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 7, 2022
Decision date	Jul 28, 2023
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mesi, Development of Medical Devices, Ltd.; Mesi D.O.O.
Location	Ljubljana, SI
Contact	Jakob Susteric
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Paladin Medical, Inc.
Contact	Elaine Duncan

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

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