

**K213730 MESI mTABLET TBI diagnostic system, MESI mTABLET TBI**Apr 21, 2022  
146 days to decisionK213730 · Product code: **JOM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213730/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic (JOM)
Date received	Nov 26, 2021
Decision date	Apr 21, 2022
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Paladin Medical, Inc.</b>
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)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213730/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026