

K201046 Automated ankle brachial pressure index measuring device, MESI mTABLET systemDec 11, 2020
234 days to decisionK201046 · Product code: **JOM** · Cardiovascular
Source: <https://www.510kdatabase.net/k201046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic (JOM)
Date received	Apr 21, 2020
Decision date	Dec 11, 2020
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mesi D.O.O.; Mesi, Development of Medical Devices, Ltd.
Location	Ljubljana, SI
Contact	Jakob Susteric
510(k) history	2 submissions · 2 cleared · 2018-2020

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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201046/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026