FDA 510(k) Premarket Notification

CLEARED

K172655 Automated ankle brachial pressure index measuring device

Jan 11, 2018
128 days to decision

K172655 · Product code: **JOM** · Cardiovascular
Source: https://www.510kdatabase.net/k172655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic (JOM)
Date received	Sep 5, 2017
Decision date	Jan 11, 2018
Days to decision	128 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