FDA 510(k) Premarket Notification

K201635 MouthLab Vital Signs Monitoring System

CLEARED

Feb 6, 2021
235 days to decision

K201635 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k201635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jun 16, 2020
Decision date	Feb 6, 2021
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Multisensor Diagnostics (Dba Aidar Health)**
Location	Pikesville, MD, US
Contact	Sathya Elumalai
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov