

K191266 VitalScan ANSJan 15, 2020
250 days to decisionK191266 · Product code: **JOM** · Cardiovascular
Source: <https://www.510kdatabase.net/k191266/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plethysmograph, Photoelectric, Pneumatic Or Hydraulic (JOM) |
| Date received | May 10, 2019 |
| Decision date | Jan 15, 2020 |
| Days to decision | 250 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medeia, Inc. |
| Location | Miami, FL, US |
| Contact | Slav Danev |
| 510(k) history | 4 submissions · 4 cleared · 2015-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191266/> 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 May 27, 2026