

K241086 Avidhrt Sense SpO2May 9, 2025
385 days to decisionK241086 · Product code: **DQA** · Cardiovascular
Source: <https://www.510kdatabase.net/k241086/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | Apr 19, 2024 |
| Decision date | May 9, 2025 |
| Days to decision | 385 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Avidhrt, Inc. |
| Location | East Lansing, MI, US |
| Contact | Prabode Weebadde |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------|
| Consulting firm | Mdqr, LLC |
| Contact | Raghavan Prabhu |

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/k241086/> 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 13, 2026