

K223399 AViTA Pulse OximeterMay 20, 2024
558 days to decisionK223399 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k223399/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | Nov 9, 2022 |
| Decision date | May 20, 2024 |
| Days to decision | 558 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Avita Corporation |
| Location | New Taipei City, CN |
| Contact | Joanna Lin |
| Website | https://www.avita.com.tw |
| 510(k) history | 26 submissions · 26 cleared · 2000-2026 |

Avita Corporation is a medical device manufacturer based in New Taipei City, China. The company specializes in home care and clinical monitoring devices. Avita has received FDA 510(k) clearances from total submissions since 2000. The company's cleared devices span cardiovascular monitoring, anesthesiology, and general hospital applications. The latest clearance was in 2026, demonstrating continued regulatory activity and product innovation. The company's product portfolio includes blood pressure monitors, pulse oximeters, infrared thermometers, nasal aspirators, nebulizer...