

K242455 AViTA Pulse Oximeter (SP62B)Feb 19, 2025
184 days to decisionK242455 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k242455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 19, 2024
Decision date	Feb 19, 2025
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avita Corporation
Location	New Taipei City, CN
Contact	Maggie Chao
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...