FDA 510(k) Premarket Notification

K252448 AViTA Pulse Oximeter (SP61)

CLEARED

Feb 27, 2026
207 days to decision

K252448 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k252448/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 4, 2025
Decision date	Feb 27, 2026
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Avita Corporation**
Location	New Taipei City, CN
Contact	Hsieh Rex
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...