

**K250129 AViTA Breast Pump**Jun 11, 2026  
510 days to decisionK250129 · Product code: **HGX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k250129/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jan 17, 2025
Decision date	Jun 11, 2026
Days to decision	510 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Avita Corporation</b>
Location	New Taipei City, CN
Contact	Rex Hsieh
Website	<a href="https://www.avita.com.tw">https://www.avita.com.tw</a>
510(k) history	27 submissions · 27 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...

---