

K092958 AVITA SCANEO IR THERMOMETER, MODELS TS2X & TS3X SERIESDec 2, 2009
68 days to decisionK092958 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k092958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 25, 2009
Decision date	Dec 2, 2009
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avita Corporation
Location	New Taipei City, CN
Contact	JENNIFER REICH
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...