

K251160 Sterile temperature probe (Model: W0001ES, W0028ES, W0101FS-A, W0101FS-P, W0099LS, W0099FS, W0099PS)Jan 8, 2026
268 days to decisionK251160 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k251160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 15, 2025
Decision date	Jan 8, 2026
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Med-Link Electronics Tech Co., Ltd.
Location	Nederland, CO, US
Contact	Summer Xia
510(k) history	14 submissions · 14 cleared · 2009-2026

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