

K251138 Promisemed Safety Huber NeedlesMay 13, 2025
29 days to decisionK251138 · Product code: **PTI** · General HospitalSource: <https://www.510kdatabase.net/k251138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Non-coring (huber) Needle (PTI)
Date received	Apr 14, 2025
Decision date	May 13, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Promisemed Hangzhou Meditech Co., Ltd.
Location	Hangzhou, CN
Contact	Zearou Yang
510(k) history	34 submissions · 34 cleared · 2017-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026