

K243332 Promisemed Safety Huber NeedlesMar 14, 2025
141 days to decisionK243332 · Product code: **PTI** · General HospitalSource: <https://www.510kdatabase.net/k243332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Non-coring (huber) Needle (PTI)
Date received	Oct 24, 2024
Decision date	Mar 14, 2025
Days to decision	141 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

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