

**K193009 Promisemed Heel Blood Lancet**Dec 3, 2019  
36 days to decisionK193009 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193009/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Oct 28, 2019
Decision date	Dec 3, 2019
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193009/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026