

**K232450 Disposable Hemostatic Clips**Jan 26, 2024  
165 days to decisionK232450 · Product code: **PKL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k232450/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Aug 14, 2023
Decision date	Jan 26, 2024
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Soudon Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Junshi Wang
510(k) history	4 submissions · 4 cleared · 2023-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Vanhe Consulting Co., Ltd.</b>
Contact	Nick Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232450/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026