

**K230004 Disposable Hemoclip**Jul 31, 2023  
209 days to decisionK230004 · Product code: **PKL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k230004/>**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	Jan 3, 2023
Decision date	Jul 31, 2023
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Yangzhou Fartley Medical Instrument Technology Co., Ltd.</b>
Location	Yangzhou, CN
Contact	Tina Han
510(k) history	7 submissions · 7 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230004/> 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 25, 2026