

K250643 Disposable Polymer Ligation ClipsNov 20, 2025
261 days to decisionK250643 · Product code: **FZP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clip, Implantable (FZP)
Date received	Mar 4, 2025
Decision date	Nov 20, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Kangji Medical Instrument Co., Ltd.
Location	Hangzhou, CN
Contact	Martin Sun
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Lingfu Technology Co., Ltd.
Contact	Esther Zhang

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.netDevice record: <https://www.510kdatabase.net/k250643/> 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 14, 2026