

K231633 Disposable Hemoclip (AF series)Jan 11, 2024
220 days to decisionK231633 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Jun 5, 2023
Decision date	Jan 11, 2024
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alton (Shanghai) Medical Instruments Co., Ltd.
Location	Shanghai, CN
Contact	Vivian Li
510(k) history	6 submissions · 6 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231633/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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