

K213143 HemoclipJul 12, 2022
288 days to decisionK213143 · Product code: **PKL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Sep 27, 2021
Decision date	Jul 12, 2022
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou AGS MedTech Co., Ltd.
Location	Hangzhou, CN
Contact	Yanping Fu
510(k) history	17 submissions · 17 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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