

K254050 Manual Tissue Removal DeviceMay 15, 2026
149 days to decisionK254050 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k254050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Dec 17, 2025
Decision date	May 15, 2026
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou AcuVu Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Sam Mostafavi
510(k) history	2 submissions · 2 cleared · 2024-2026

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