

**K240978 SeleneView® Single-Use Digital Hysteroscope (HC29, HC29-G, HC35, HC35-G, HO35, HO35-G, HO42, HO42-G)**Aug 16, 2024  
128 days to decisionK240978 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k240978/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 10, 2024
Decision date	Aug 16, 2024
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>MacroLux Medical Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Linbin Ye
510(k) history	6 submissions · 6 cleared · 2024-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240978/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026