

**K213317 ShinEvac Smoke Evacuation Pencil**Jan 28, 2022  
116 days to decisionK213317 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 4, 2021
Decision date	Jan 28, 2022
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shining World Health Care Co., Ltd.</b>
Location	Hsin Chu City, TW
Contact	Anita Chen
510(k) history	4 submissions · 4 cleared · 1999-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213317/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026