

**K182354 SafeAir Telescopic Smoke Pencil**Dec 14, 2018  
107 days to decisionK182354 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 29, 2018
Decision date	Dec 14, 2018
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lina Medical Aps</b>
Location	Chapel Hill, NC, US
Contact	Natalia Szychulska
510(k) history	16 submissions · 16 cleared · 2006-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182354/> 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 26, 2026