

**K253550 Self-Forming Magnet (Flexagon Plus OTOLoc)**Jan 9, 2026  
56 days to decisionK253550 · Product code: **SAH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetic Compression Anastomosis System (SAH)
Date received	Nov 14, 2025
Decision date	Jan 9, 2026
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GI Windows, Inc.</b>
Location	Westwood, MA, US
Contact	Westwood Bobay
510(k) history	4 submissions · 4 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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