

K250541 Self-Forming Magnet (Flexagon Plus OTOLoc)Aug 1, 2025
158 days to decisionK250541 · Product code: **SAH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetic Compression Anastomosis System (SAH)
Date received	Feb 24, 2025
Decision date	Aug 1, 2025
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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