

K251433 Surgify Halo (54.085.SHD.H1)Jun 4, 2025
27 days to decisionK251433 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k251433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	May 8, 2025
Decision date	Jun 4, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Surgify Halo (54.140.SHD.H1); Surgify Halo (54.070.NVG.H1); Surgify Halo (54.125.NVG.H1); Surgify Halo (54.000.SEE.H1); Surgify Halo (40.070.NVG.H1); Surgify Halo (40.125.NVG.H1); Surgify Halo (40.000.SEE.H1)

APPLICANT

Company	Surgify Medical OY
Location	Espoo, FI
Contact	Jukka Kreander
510(k) history	4 submissions · 4 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Avania, LLC
Contact	Richard Lilly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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