FDA 510(k) Premarket Notification

K250380 Surgify Halo (54.085.SHD.H1)

CLEARED

Mar 13, 2025
30 days to decision

K250380 · Product code: **HBE** · Neurology
Source: https://www.510kdatabase.net/k250380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Feb 11, 2025
Decision date	Mar 13, 2025
Days to decision	30 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)

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

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