

K253627 Surgify Halo (54.085.SHD.U1)Mar 26, 2026
127 days to decisionK253627 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k253627/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE) |
| Date received | Nov 19, 2025 |
| Decision date | Mar 26, 2026 |
| Days to decision | 127 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Surgify Halo (54.140.SHD.U1); Surgify Halo (54.070.NVG.U1); Surgify Halo (54.125.NVG.U1); Surgify Halo (54.000.SEE.U1); Surgify Halo (40.070.NVG.U1); Surgify Halo (40.125.NVG.U1); Surgify Halo (40.000.SEE.U1); Surgify Halo (30.070.NVG.U2); Surgify Halo (30.125.NVG.U2); Surgify Halo (30.000.SEE.U2) |

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)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253627/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026