

K232684 Surgify HaloNov 29, 2023
89 days to decisionK232684 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k232684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Sep 1, 2023
Decision date	Nov 29, 2023
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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