

K182527 ELAN 4 ToolsJan 19, 2019
127 days to decisionK182527 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k182527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Sep 14, 2018
Decision date	Jan 19, 2019
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap, Inc.
Location	Burlingame, CA, US
Contact	Kathy A. Racosky
510(k) history	207 submissions · 201 cleared · 1991-2025

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