

K183203 ELAN 4 ToolsAug 9, 2019
263 days to decisionK183203 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k183203/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Nov 19, 2018
Decision date	Aug 9, 2019
Days to decision	263 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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