

K223596 SQ.line KERRISONJun 29, 2023
209 days to decisionK223596 · Product code: **HAE** · Neurology
Source: <https://www.510kdatabase.net/k223596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rongeur, Manual (HAE)
Date received	Dec 2, 2022
Decision date	Jun 29, 2023
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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