

K200387 Ace Medical Surgical InstrumentsJul 21, 2020
154 days to decisionK200387 · Product code: **HAE** · Neurology
Source: <https://www.510kdatabase.net/k200387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rongeur, Manual (HAE)
Date received	Feb 18, 2020
Decision date	Jul 21, 2020
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ace Medical
Location	Cincinnati, OH, US
Contact	Alex Ebner
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Jalex Medical
Contact	Cassie Petrov

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200387/> 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 June 28, 2026