

**K200383 Wiggins Medical Surgical Instruments**Jul 21, 2020  
154 days to decisionK200383 · Product code: **HAE** · Neurology  
Source: <https://www.510kdatabase.net/k200383/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| 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**

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|----------------|---------------------------------------|
| Company        | <b>Wiggins Medical</b>                |
| Location       | Cincinnati, OH, US                    |
| Contact        | Alex Ebner                            |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------|
| Consulting firm | <b>Jalex Medical</b> |
| Contact         | Cassandra Petrov     |

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

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