

**K170442 Cranial Drill Bits and Accessories**Sep 7, 2017  
205 days to decisionK170442 · Product code: **HBE** · Neurology  
Source: <https://www.510kdatabase.net/k170442/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                             |
| Submission type       | Traditional  |
| Device classification | Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE) |
| Date received         | Feb 14, 2017   |
| Decision date         | Sep 7, 2017  |
| Days to decision      | 205 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ad-Tech Medical Instrument Corporation</b> |
| Location       | Racine, WI, US                                |
| Contact        | Lisa Theama                                   |
| 510(k) history | 8 submissions · 8 cleared · 2016-2023         |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170442/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026