

K172907 ELAN 4 Air Motor SystemNov 9, 2018
410 days to decisionK172907 · Product code: **HBB** · Neurology
Source: <https://www.510kdatabase.net/k172907/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Motor, Drill, Pneumatic (HBB) |
| Date received | Sep 25, 2017 |
| Decision date | Nov 9, 2018 |
| Days to decision | 410 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172907/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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