

K252696 LEGACYNov 21, 2025
86 days to decisionK252696 · Product code: **HBG** · Neurology
Source: <https://www.510kdatabase.net/k252696/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drills, Burrs, Trephines & Accessories (manual) (HBG) |
| Date received | Aug 27, 2025 |
| Decision date | Nov 21, 2025 |
| Days to decision | 86 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Phasor Health, LLC |
| Location | Houston, TX, US |
| Contact | Ray King |
| 510(k) history | 5 submissions · 4 cleared · 2025-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252696/> 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 May 13, 2026