

K252338 MySleepDashApr 17, 2026
263 days to decisionK252338 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k252338/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received | Jul 28, 2025 |
| Decision date | Apr 17, 2026 |
| Days to decision | 263 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Somnetics International, Inc. (Dba Transcend Inc) |
| Location | Fridley, MN, US |
| Contact | William Brown |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252338/> 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 14, 2026