

**K172986 Zmachine Synergy**Dec 19, 2017  
83 days to decisionK172986 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k172986/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                       |
| Submission type       | Traditional  |
| Device classification | Standard Polysomnograph With Electroencephalograph (OLV) |
| Date received         | Sep 27, 2017   |
| Decision date         | Dec 19, 2017   |
| Days to decision      | 83 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Consolidated Research of Richmond, Inc. Db a General Sleep CO</b> |
| Location       | Cleveland, OH, US  |
| Contact        | Richard Kaplan   |
| 510(k) history | 1 submissions · 1 cleared · 2017-2017                                |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172986/> 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 31, 2026