

**K132003 WINX SLEEP THERAPY SYSTEM**Jun 13, 2014  
347 days to decisionK132003 · Product code: **OZR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k132003/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Intraoral Pressure Gradient Device (OZR) |
| Date received         | Jul 1, 2013                              |
| Decision date         | Jun 13, 2014                             |
| Days to decision      | 347 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Apnicure, Inc.</b>                 |
| Location       | Redwood City, CA, US                  |
| Contact        | CHRIS DANIEL                          |
| 510(k) history | 4 submissions · 4 cleared · 2012-2014 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132003/> 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 24, 2026