

**K161832 O2VENT T**Sep 23, 2016  
80 days to decisionK161832 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k161832/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Device, Anti-snoring (LRK)         |
| Date received         | Jul 5, 2016                        |
| Decision date         | Sep 23, 2016                       |
| Days to decision      | 80 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Oventus Manufacturing Pty, Ltd.</b> |
| Location       | Brisbane, AU                           |
| Contact        | HEMANGI MALDE                          |
| 510(k) history | 4 submissions · 4 cleared · 2016-2019  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161832/> 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 June 28, 2026