

K231663 The AVEOtsd (Tongue Stabilizing Device) MouthpieceSep 18, 2023
103 days to decisionK231663 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k231663/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Jun 7, 2023 |
| Decision date | Sep 18, 2023 |
| Days to decision | 103 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Innovative Health Technologies (Nz), Ltd. |
| Location | Dunedin, NZ |
| Contact | Chapman Philip |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231663/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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