FDA 510(k) Premarket Notification

# K250353 Oniris

**CLEARED**

Sep 4, 2025
209 days to decision

K250353 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k250353/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Feb 7, 2025 |
| Decision date | Sep 4, 2025 |
| Days to decision | 209 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Oniris Plus |

## APPLICANT

| | |
|---|---|
| Company | **Oniris** |
| Location | Rueil Malmaison, FR |
| Contact | Maria Markarova |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Alizée Mareczko** |
| Contact | Maria Markarova |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov