

K250353 OnirisSep 4, 2025
209 days to decisionK250353 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k250353/>**SUBMISSION DETAILS**

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](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250353/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026