

K241283 Elemental GranulateJan 3, 2025
241 days to decisionK241283 · Product code: **OLR** · Dental
Source: <https://www.510kdatabase.net/k241283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	May 7, 2024
Decision date	Jan 3, 2025
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zinkh NV
Location	Gent, BE
Contact	Emiel Lippens
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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