

K233808 LW Narrow Implant SystemJul 31, 2024
244 days to decisionK233808 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k233808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 30, 2023
Decision date	Jul 31, 2024
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ossvis Co., Ltd.
Location	Anyang-Si, KR
Contact	Woo Jin Lee
510(k) history	7 submissions · 7 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233808/> 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