FDA 510(k) Premarket Notification

K233808 LW Narrow Implant System

CLEARED

Jul 31, 2024
244 days to decision

K233808 · 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