FDA 510(k) Premarket Notification

K233163 ZENEX Implant System_Short

CLEARED

Dec 19, 2023
83 days to decision

K233163 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k233163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 27, 2023
Decision date	Dec 19, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Izenimplant Co., Ltd.**
Location	Pyeongtaek-Si, KR
Contact	Mi-Kyung Kwon
510(k) history	8 submissions · 8 cleared · 2022-2026

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