FDA 510(k) Premarket Notification

K243078 HexaPLUS S OneDrill Implant System

CLEARED

Oct 10, 2025
375 days to decision

K243078 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k243078/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 30, 2024
Decision date	Oct 10, 2025
Days to decision	375 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osseofuse International, Inc.**
Location	Calabasas, CA, US
Contact	Priscilla Chung
510(k) history	2 submissions · 2 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov