FDA 510(k) Premarket Notification

K233271 OsseOne Dental Implant System

CLEARED

May 8, 2025
587 days to decision

K233271 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k233271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 29, 2023
Decision date	May 8, 2025
Days to decision	587 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Synoross Dba Osseone**
Location	Glendale, CA, US
Contact	Gennady Shapiro
510(k) history	2 submissions · 2 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

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