

**K233271 OsseOne Dental Implant System**May 8, 2025  
587 days to decisionK233271 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k233271/>**SUBMISSION DETAILS**

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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**

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Company	<b>Synoross DbA Osseone</b>
Location	Glendale, CA, US
Contact	Gennady Shapiro
510(k) history	2 submissions · 2 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Blackwell Device Consulting</b>
Contact	Angela Blackwell

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233271/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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