

**K250271 Neodent Implant System - Zirconia Implant System**Aug 18, 2025  
200 days to decisionK250271 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k250271/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 30, 2025
Decision date	Aug 18, 2025
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>JJGC Ind?stria e Com?rcio de Materiais Dent?rios S.A.</b>
Location	Curitiba, BR
Contact	Leticia Milani
510(k) history	10 submissions · 10 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Straumann USA, LLC</b>
Contact	Jennifer Jackson

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

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