

**K190958 Neodent Implant System**Nov 9, 2019  
211 days to decisionK190958 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k190958/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 12, 2019
Decision date	Nov 9, 2019
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jjgc Industria E Comercio DE Materiais Dentarios S.A.</b>
Location	Curitiba, BR
Contact	Mariana Soares Hartmann
510(k) history	28 submissions · 28 cleared · 2016-2023

**REGULATORY CONSULTANT**

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

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

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