

**K201225 Neodent Implant System - GM Helix Implants 7.0**Sep 4, 2020  
121 days to decisionK201225 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k201225/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 6, 2020
Decision date	Sep 4, 2020
Days to decision	121 days
Third-party review	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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201225/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026