

K250614 Neodent Implant System - Custom AbutmentsMay 27, 2025
88 days to decisionK250614 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k250614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Feb 28, 2025
Decision date	May 27, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jjgc Ind?stria E Com?rcia DE Materiais Dent?rios S.A.
Location	Curitiba, BR
Contact	Leticia Milani
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer Jackson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250614/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026