

K214051 Neodent Implant System-Helix NGM Compact Surgical Kit CasesApr 13, 2022
107 days to decisionK214051 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k214051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Dec 27, 2021
Decision date	Apr 13, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	JJGC Indústria e Comércio de Materiais Dentários S.A.
Location	Curitiba, BR
Contact	Thais Barboza
510(k) history	10 submissions · 10 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer M. Jackson

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

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