

**K223662 Neodent Implant System - Helix Short Surgical Kit
Cases**Apr 20, 2023
135 days to decisionK223662 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k223662/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Dec 6, 2022
Decision date	Apr 20, 2023
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jjgc Industria E Comercio DE Materiais Dentarios S.A.
Location	Curitiba, BR
Contact	Barbara Uzae
510(k) history	28 submissions · 28 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer M. Jackson, MS

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/k223662/> 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