

K182865 Neodent Instruments KitsMay 7, 2019
208 days to decisionK182865 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k182865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Oct 11, 2018
Decision date	May 7, 2019
Days to decision	208 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	Julianne de Oliveira Capucho Lechechem
510(k) history	28 submissions · 28 cleared · 2016-2023

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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