

K230804 Complement Kit CasesJul 7, 2023
106 days to decisionK230804 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k230804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Mar 23, 2023
Decision date	Jul 7, 2023
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	JJGC Ind?stria e Com?rcio de Materiais Dent?rios S.A.
Location	Curitiba, BR
Contact	Barbara Uzae
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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