

K203198 KARL STORZ Metal Sterilization TraysJul 6, 2021
250 days to decisionK203198 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k203198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Oct 29, 2020
Decision date	Jul 6, 2021
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	Leigh Spotten
510(k) history	361 submissions · 361 cleared · 1980-2024

REGULATORY CONSULTANT

Consulting firm	Toscano Consulting
Contact	David Furr

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203198/> 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 13, 2026