

K201945 KARL STORZ UDEL Sterilization TraysFeb 25, 2021
227 days to decisionK201945 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k201945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jul 13, 2020
Decision date	Feb 25, 2021
Days to decision	227 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

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