

K201878 ST-Z5Mar 25, 2021
261 days to decisionK201878 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k201878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jul 7, 2020
Decision date	Mar 25, 2021
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Z-Systems AG
Location	San Diego, CA, US
Contact	Rubino DiGirolamo
510(k) history	9 submissions · 9 cleared · 2007-2021

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin A Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201878/> 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 27, 2026