

K243425 Guided DAS Surgical KitJul 22, 2025
260 days to decisionK243425 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k243425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Nov 4, 2024
Decision date	Jul 22, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Talladium Espa?a, SL
Location	Lleida, ES
Contact	Xavier Soca Filella
510(k) history	7 submissions · 7 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Rebecca Kattan

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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