

K243128 Klockner KitsDec 18, 2024
79 days to decisionK243128 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k243128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Sep 30, 2024
Decision date	Dec 18, 2024
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SOADCO, S.L.
Location	Escaldes-Engordany, AD
Contact	Mercedes Roldan
510(k) history	11 submissions · 11 cleared · 2002-2024

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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