

**K243589 PAL Sterilization Case**Jun 20, 2025  
212 days to decisionK243589 · Product code: **KCT** · General Hospital  
Source: <https://www.510kdatabase.net/k243589/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Nov 20, 2024
Decision date	Jun 20, 2025
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Microaire Surgical Instruments, LLC</b>
Location	Chesterfield, VA, US
Contact	Glenn Gerstenfeld
Website	<a href="https://www.microaire.com">https://www.microaire.com</a>
510(k) history	9 submissions · 9 cleared · 2012-2025

Microaire Surgical Instruments, LLC designs and manufactures surgical devices for General & Plastic Surgery and related specialties. The company operates with a manufacturing facility in Chesterfield, US, and serves surgeons globally through an established distribution network. Microaire has received FDA 510(k) clearances from total submissions since 2012. General & Plastic Surgery devices represent the dominant focus, accounting for 78% of regulatory submissions. The company remains active, with its most recent clearance in 2025. The company's product portfolio centers o...