

K243431 Medicom Sterilization Pouch and ReelFeb 21, 2025
108 days to decisionK243431 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k243431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Nov 5, 2024
Decision date	Feb 21, 2025
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medicom Asia-Pacific Holdings Ltd. Taiwan Branch.
Location	Yilan County, TW
Contact	Kristy Lee
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Sen MU Technology Co., Ltd.
Contact	Uta Shih

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243431/> 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 13, 2026