

**K222440 Vis-U-All Low Temperature Sterilization Pouches/Tubing, PRO-LITE Sterilization Trays**Sep 9, 2022  
28 days to decisionK222440 · Product code: **FRG** · General HospitalSource: <https://www.510kdatabase.net/k222440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wrap, Sterilization (FRG)
Date received	Aug 12, 2022
Decision date	Sep 9, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Steris</b>
Location	Mentor, OH, US
Contact	Anthony Piotrkowski
Website	<a href="https://www.steris.com">https://www.steris.com</a>
510(k) history	21 submissions · 19 cleared · 2021-2026

Steris is a leading global provider of products and services supporting patient care with emphasis on infection prevention. The company operates with a manufacturing facility in Mentor, Ohio, and serves hospitals, surgery centers, pharmaceutical manufacturers, and research laboratories worldwide. Steris has received FDA 510(k) clearances from total submissions since 2021. The company specializes in General Hospital devices, which represent 81% of its regulatory submissions. Recent clearances include sterilization systems, chemical indicators, biological indicators, and wa...