

**K233065 V-PRO maX 2 Low Temperature Sterilization System**Oct 20, 2023  
24 days to decisionK233065 · Product code: **MLR** · General Hospital  
Source: <https://www.510kdatabase.net/k233065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilizer, Chemical (MLR)
Date received	Sep 26, 2023
Decision date	Oct 20, 2023
Days to decision	24 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	Jennifer Nalepka
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...