

**K242732 Tristel OPH**May 9, 2025  
241 days to decisionK242732 · Product code: **QWS** · General Hospital  
Source: <https://www.510kdatabase.net/k242732/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Foam Or Gel Chemical Sterilant/high Level Disinfectant (QWS)
Date received	Sep 10, 2024
Decision date	May 9, 2025
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tristel Solutions , Ltd.</b>
Location	Cambridgeshire, GB
Contact	Julija Shabanova
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242732/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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