

K252128 Zener® (model ZEN-001-B1)Sep 15, 2025
70 days to decisionK252128 · Product code: **FRA** · General Hospital
Source: <https://www.510kdatabase.net/k252128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Jul 7, 2025
Decision date	Sep 15, 2025
Days to decision	70 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Uvx, Inc.
Location	Vancouver, CA
Contact	Kunal Sethi
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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