

K232976 VUZE SystemMay 9, 2024
231 days to decisionK232976 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k232976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 21, 2023
Decision date	May 9, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vuze Medical , Ltd.
Location	Ra'Anana, IL
Contact	David Tolkowsky
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Shriner & Associates, Inc.
Contact	Clay Anselmo

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

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