FDA 510(k) Premarket Notification

K210830 VUZE System

CLEARED

Jan 3, 2022
290 days to decision

K210830 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k210830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 19, 2021
Decision date	Jan 3, 2022
Days to decision	290 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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Device record: https://www.510kdatabase.net/k210830/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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