

K232789 VIO System (V-1000)Dec 22, 2023
102 days to decisionK232789 · Product code: **QZN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k232789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-photon Imaging (QZN)
Date received	Sep 11, 2023
Decision date	Dec 22, 2023
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enspectra Health, Inc.
Location	Mountain View, CA, US
Contact	Grace Li
510(k) history	1 submissions · 1 cleared · 2023-2023

CLINICAL EVIDENCE - NCT05619471**VIO Imaging for Skin Tissue Assessment (VISTA)**

Status	Completed
Enrollment	65 patients (actual)
Study sites	2 sites
Condition studied	Skin Condition; Skin Diseases; Skin Lesion; Skin Abnormalities; Skin Cancer
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 11, 2023
Sponsor	Enspectra Health (Industry)

Primary outcome

Comparative Reader Percentage Agreement

Secondary outcome

Inter-Reader Percentage Agreement

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05619471