CLEARED

K260324 Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning

May 22, 2026
112 days to decision

K260324 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k260324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 30, 2026
Decision date	May 22, 2026
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Canon Medical Informatics, Inc.**
Location	Minnetonka, MN, US
Contact	Jay Vaishnav
510(k) history	5 submissions · 5 cleared · 2022-2026