

**K260324 Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning**May 22, 2026  
112 days to decisionK260324 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k260324/>**SUBMISSION DETAILS**

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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**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260324/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 8, 2026