

K253786 syngo.CT Coronary CockpitJun 25, 2026
211 days to decisionK253786 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k253786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 26, 2025
Decision date	Jun 25, 2026
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Kenny M Bello
510(k) history	782 submissions · 782 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253786/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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