

K251837 Salix Coronary Plaque (V1.0.0)Aug 20, 2025
65 days to decisionK251837 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 16, 2025
Decision date	Aug 20, 2025
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Artrya Limited
Location	Perth, AU
Contact	Gabriela Quijada
510(k) history	2 submissions · 2 cleared · 2025-2025

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