

K243859 PRAEVAorta®2Aug 29, 2025
256 days to decisionK243859 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 16, 2024
Decision date	Aug 29, 2025
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nurea
Location	B?gles, FR
Contact	Lamia Stephan
510(k) history	1 submissions · 1 cleared · 2025-2025

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