

K182611 Qangio XA 3DMay 30, 2019
251 days to decisionK182611 · Product code: **QHA** · Radiology
Source: <https://www.510kdatabase.net/k182611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray Angiographic Imaging Based Coronary Vascular Simulation Software Device (QHA)
Date received	Sep 21, 2018
Decision date	May 30, 2019
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medis Medical Imaging Systems BV
Location	Leiden, NL
Contact	B. Goedhart
510(k) history	17 submissions · 17 cleared · 1999-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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