

K211788 HALOJul 8, 2021
29 days to decisionK211788 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k211788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Jun 9, 2021
Decision date	Jul 8, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nicolab B.V.
Location	Amsterdam, NL
Contact	Merel Boers
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	MD Squared BV
Contact	Ruojuan Zhang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211788/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026