

K252214 AIAS CephalonOct 7, 2025
84 days to decisionK252214 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 15, 2025
Decision date	Oct 7, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Metamorphosis GmbH
Location	Paderborn, DE
Contact	Dr. Stefanie Horstmann
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252214/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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