

K243005 AudaxCeph Cephalogram Analysis SoftwareMay 30, 2025
246 days to decisionK243005 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 26, 2024
Decision date	May 30, 2025
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Audax D.O.O.
Location	Ljubljana, SI
Contact	Peter Kobal
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Trellis Enterprises, LLC
Contact	Josh Ellis

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

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