FDA 510(k) Premarket Notification

K250694 Scaida BrainCT-ICH (v1.0)

CLEARED

Nov 25, 2025
263 days to decision

K250694 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k250694/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Mar 7, 2025
Decision date	Nov 25, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mlhealth 360**
Location	Surrey, CA
Contact	Kumar Surender Sinwar
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Product Success, Inc.**
Contact	Sujata Ghatpande

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