

K253884 Koios DS (3.8)

Jul 2, 2026
210 days to decision

K253884 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k253884/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Dec 4, 2025
Decision date	Jul 2, 2026
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Koios Medical, Inc.
Location	New York, NY, US
Contact	Michael Bocchinfuso
510(k) history	4 submissions · 4 cleared · 2019-2026