

K212616 Koios DSDec 16, 2021
120 days to decisionK212616 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k212616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Aug 18, 2021
Decision date	Dec 16, 2021
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Koios Medical, Inc.
Location	New York, NY, US
Contact	Patricia Setti-Laperch
510(k) history	3 submissions · 3 cleared · 2019-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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