FDA 510(k) Premarket Notification

K212616 Koios DS

CLEARED

Dec 16, 2021
120 days to decision

K212616 · 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