FDA 510(k) Premarket Notification

K190442 Koios DS for Breast

CLEARED

Jul 3, 2019
128 days to decision

K190442 · Product code: **POK** · Radiology
Source: https://www.510kdatabase.net/k190442/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Feb 25, 2019
Decision date	Jul 3, 2019
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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