

**K190442 Koios DS for Breast**Jul 3, 2019  
128 days to decisionK190442 · Product code: **POK** · Radiology  
Source: <https://www.510kdatabase.net/k190442/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190442/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026