

**K242130 Koios DS**Nov 15, 2024  
116 days to decisionK242130 · Product code: **POK** · Radiology  
Source: <https://www.510kdatabase.net/k242130/>**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         | Jul 22, 2024  |
| Decision date         | Nov 15, 2024  |
| Days to decision      | 116 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Koios Medical, Inc.</b>            |
| Location       | New York, NY, US                      |
| Contact        | Michael Bocchinfuso                   |
| 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/k242130/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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