

**K203629 IDx-DR**Jun 10, 2021  
181 days to decisionK203629 · Product code: **PIB** · Ophthalmic  
Source: <https://www.510kdatabase.net/k203629/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Diabetic Retinopathy Detection Device (PIB) |
| Date received         | Dec 11, 2020                                |
| Decision date         | Jun 10, 2021                                |
| Days to decision      | 181 days                                    |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                     |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Digital Diagnostics, Inc.</b>      |
| Location       | Coralville, IA, US                    |
| Contact        | Ashley Miller                         |
| 510(k) history | 2 submissions · 2 cleared · 2021-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203629/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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