FDA 510(k) Premarket Notification

# K203629 IDx-DR

**CLEARED**

Jun 10, 2021
181 days to decision

K203629 · Product code: **PIB** · Ophthalmic
Source: https://www.510kdatabase.net/k203629/

## SUBMISSION DETAILS

| | |
|---|---|
| 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

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