

K213037 IDx-DR v2.3Jun 17, 2022
269 days to decisionK213037 · Product code: **PIB** · Ophthalmic
Source: <https://www.510kdatabase.net/k213037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diabetic Retinopathy Detection Device (PIB)
Date received	Sep 21, 2021
Decision date	Jun 17, 2022
Days to decision	269 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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Kelliann Payne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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