

K231852 BinkieRTNov 15, 2023
145 days to decisionK231852 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k231852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jun 23, 2023
Decision date	Nov 15, 2023
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Papricalab
Location	Seoul, KR
Contact	Sohyeon Woo
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Gms Consulting
Contact	Jonghyum Kim

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

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