FDA 510(k) Premarket Notification

K231466 RxSight Insertion Device

CLEARED

Jun 12, 2023
24 days to decision

K231466 · Product code: **MSS** · Ophthalmic
Source: https://www.510kdatabase.net/k231466/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	May 19, 2023
Decision date	Jun 12, 2023
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rxsight, Inc.**
Location	Aliso Viejo, CA, US
Contact	Maureen O'Connell
510(k) history	5 submissions · 5 cleared · 2018-2023