FDA 510(k) Premarket Notification

K242389 EyeGility™ Inserter for Preloaded enVista IOLs

CLEARED

Oct 10, 2024
59 days to decision

K242389 · Product code: **MSS** · Ophthalmic
Source: https://www.510kdatabase.net/k242389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Aug 12, 2024
Decision date	Oct 10, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Incorporated**
Location	Rochester, NY, US
Contact	Renee Stoffel
510(k) history	27 submissions · 27 cleared · 2002-2024