FDA 510(k) Premarket Notification

K230722 Eagle device

CLEARED

Dec 8, 2023
267 days to decision

K230722 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k230722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Mar 16, 2023
Decision date	Dec 8, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Belkin Vision, Ltd.**
Location	Yavne, IL
Contact	Daria Lemann-Blumenthal
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**Regulatory Pathways Group, Inc.**
Contact	Anne-Marie Ripley

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