

K230722 Eagle deviceDec 8, 2023
267 days to decisionK230722 · 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

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