

K220974 R:GENDec 27, 2022
267 days to decisionK220974 · Product code: **HQF** · Ophthalmic
Source: <https://www.510kdatabase.net/k220974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Apr 4, 2022
Decision date	Dec 27, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lutronic Vision, Inc.
Location	Billerica, MA, US
Contact	Haelyung Hwang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Dulciana Chan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220974/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026