FDA 510(k) Premarket Notification

K250501 System Sophi

CLEARED

Nov 14, 2025
267 days to decision

K250501 · Product code: **HQC** · Ophthalmic
Source: https://www.510kdatabase.net/k250501/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Feb 20, 2025
Decision date	Nov 14, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**This AG**
Location	Heerbrugg, CH
Contact	Mr. Kai Kremnitzer
510(k) history	1 submissions · 1 cleared · 2025-2025

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