

K261264 Stellaris Elite™ vision enhancement systemMay 15, 2026
29 days to decisionK261264 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k261264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Phacofragmentation (HQC)
Date received	Apr 16, 2026
Decision date	May 15, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Posterior and Combined Procedure Pack(s): 23 ga. Posterior Elite™ Pack (SE5423); 23 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423B); 25 ga. Posterior Elite™ Pack (SE5425); 25 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5425B); 27 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427B); 23 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423BB+); 25 ga. Bi-Blade™+

APPLICANT

Company	Bausch and Lomb
Location	St. Louis, MO, US
Contact	Matthew Harrison
510(k) history	2 submissions · 2 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261264/> 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 June 9, 2026