

**K101325 STELLARIS PC VISION ENHANCEMENT SYSTEM**Aug 17, 2010  
97 days to decisionK101325 · Product code: **HQC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k101325/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	May 12, 2010
Decision date	Aug 17, 2010
Days to decision	97 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bausch &amp; Lomb, Inc.</b>
Location	Mchenry, IL, US
Contact	NED LUCE
Website	<a href="http://www.bausch.com">http://www.bausch.com</a>
510(k) history	92 submissions · 92 cleared · 1977-2019

Bausch & Lomb, Inc. is a Canadian eye health company founded in 1853. The company is now part of Valeant Pharmaceuticals following a 2013 acquisition. Bausch & Lomb has received FDA 510(k) clearances from total submissions since 1977. The company specializes in Ophthalmic devices, which represent 83% of its regulatory submissions. Recent cleared devices include contact lenses, intraocular lens injectors, lens delivery systems, and care solutions. The company's last FDA 510(k) clearance was in 2019, and this profile reflects its historical regulatory record. Bausch & Lomb ...

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