FDA 510(k) Premarket Notification

CLEARED

K082473 BAUSCH & LOMB STELLARIS MICROSURGICAL SYSTEM

Jan 5, 2009
131 days to decision

K082473 · Product code: **HQC** · Ophthalmic
Source: https://www.510kdatabase.net/k082473/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Unit, Phacofragmentation (HQC)
Date received	Aug 27, 2008
Decision date	Jan 5, 2009
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	NED L LUCE
Website	http://www.bausch.com
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 ...