FDA 510(k) Premarket Notification

K012435 ENTRY SITE ALIGNMENT SYSTEM MODEL # CX9626

CLEARED

Oct 2, 2001
63 days to decision

K012435 · Product code: **NGY** · Ophthalmic
Source: https://www.510kdatabase.net/k012435/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Trocar, Ophthalmic (NGY)
Date received	Jul 31, 2001
Decision date	Oct 2, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	VANADA JOHNSON
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 ...