FDA 510(k) Premarket Notification

K082944 CRYSTALSERT CRYSTALENS DELIVERY SYSTEM

CLEARED

Oct 16, 2008
14 days to decision

K082944 · Product code: **MSS** · Ophthalmic
Source: https://www.510kdatabase.net/k082944/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Oct 2, 2008
Decision date	Oct 16, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	DAVID THOMAS
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 ...