FDA 510(k) Premarket Notification

CLEARED

K173480 Crystalsert Lens Delivery System

Dec 11, 2017
28 days to decision

K173480 · Product code: **MSS** · Ophthalmic
Source: https://www.510kdatabase.net/k173480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Nov 13, 2017
Decision date	Dec 11, 2017
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	Gary Rauvola
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 ...