

K192005 Bausch + Lomb PreVue Inserter for enVista PreloadedOct 4, 2019
67 days to decisionK192005 · Product code: **MSS** · Ophthalmic
Source: <https://www.510kdatabase.net/k192005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Jul 29, 2019
Decision date	Oct 4, 2019
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bausch & Lomb, Inc.
Location	Mchenry, IL, US
Contact	Rekha Janarthanan
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 ...

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Device record: <https://www.510kdatabase.net/k192005/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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