FDA 510(k) Premarket Notification

K820511 BAUSCH & LOMB STERILE ALL PURPOSE SOLU

CLEARED

Apr 9, 1982
45 days to decision

K820511 · Product code: **HPX** · Ophthalmic
Source: https://www.510kdatabase.net/k820511/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (polymethylmethacrylate) (HPX)
Date received	Feb 23, 1982
Decision date	Apr 9, 1982
Days to decision	45 days
Third-party review	No

APPLICANT

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