FDA 510(k) Premarket Notification

K001539 RENU MULTIPLUS MULTI-PURPOSE SOLUTION

CLEARED

Jul 31, 2000
75 days to decision

K001539 · Product code: **LPN** · Ophthalmic
Source: https://www.510kdatabase.net/k001539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	May 17, 2000
Decision date	Jul 31, 2000
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	PAUL G STAPLETON
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 ...