FDA 510(k) Premarket Notification

CLEARED

K083812 REFRESH OPTIVE LENS COMFORT REWETTING DROPS

Jul 9, 2009
199 days to decision

K083812 · Product code: **LPN** · Ophthalmic
Source: https://www.510kdatabase.net/k083812/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	Dec 22, 2008
Decision date	Jul 9, 2009
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Allergan, Inc.**
Location	Walker, MI, US
Contact	BEVERLEY D VENUTI
Website	http://www.allergan.com
510(k) history	33 submissions · 33 cleared · 1982-2019

Allergan, Inc. was an American global pharmaceutical company headquartered in Walker, US. The company focused on eye care, neurosciences, medical dermatology, and medical aesthetics before ceasing independent operations in 2015. Allergan received FDA 510(k) clearances from total submissions between 1982 and 2019. The company's regulatory portfolio was dominated by Ophthalmic devices, which accounted for 88% of all submissions. Notable cleared products include the XEN Glaucoma Treatment System, REFRESH rewetting drops, and the Natrelle tissue expander for surgical applicat...