FDA 510(k) Premarket Notification

K190674 REFRESH RELIEVA For CONTACTS

CLEARED

Aug 8, 2019
146 days to decision

K190674 · Product code: **LPN** · Ophthalmic
Source: https://www.510kdatabase.net/k190674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	Mar 15, 2019
Decision date	Aug 8, 2019
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Allergan, Inc.**
Location	Walker, MI, US
Contact	Emily Huang
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...

CLINICAL EVIDENCE - NCT01844388

A Study to Compare a New Eye Drop Formulation With Refresh Contacts®

Status	Completed
Enrollment	365 patients (actual)
Study sites	1 site
Condition studied	Contact Lens Lubrication
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 2, 2013
Sponsor	Allergan (Industry)

Primary outcome

Percentage of Participants With Contact Lens Distance Visual Acuity Change From Baseline

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01844388