FDA 510(k) Premarket Notification

K981116 SOVEREIGN CATARACT EXTRACTION SYSTEM

CLEARED

May 19, 1998
53 days to decision

K981116 · Product code: **KYG** · Ophthalmic
Source: https://www.510kdatabase.net/k981116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Irrigation, Ocular Surgery (KYG)
Date received	Mar 27, 1998
Decision date	May 19, 1998
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Allergan, Inc.**
Location	Walker, MI, US
Contact	MARCIA S YAROSS, PH,D.
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...