

K003638 MOJAVE CATARACT EXTRACTION SYSTEMFeb 13, 2001
81 days to decisionK003638 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k003638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Unit, Phacofragmentation (HQC)
Date received	Nov 24, 2000
Decision date	Feb 13, 2001
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Allergan, Inc.
Location	Walker, MI, US
Contact	MARK O'CONNOR;DONNELL
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...
