

**K971186 AMO DIPLOMAX/OPSYS CONSOLE**Jun 13, 1997  
73 days to decisionK971186 · Product code: **HQC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k971186/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Apr 1, 1997
Decision date	Jun 13, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Allergan, Inc.</b>
Location	Walker, MI, US
Contact	MONIQUE M HEYNINCK-DURAN
Website	<a href="http://www.allergan.com">http://www.allergan.com</a>
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...

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