FDA 510(k) Premarket Notification

K863201 NEW USE FOR ACUVAC SUCTION RESERVOIR 400CC

CLEARED

Aug 29, 1986
10 days to decision

K863201 · Product code: **GCY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k863201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Suction, Single Patient Use, Portable, Nonpowered (GCY)
Date received	Aug 19, 1986
Decision date	Aug 29, 1986
Days to decision	10 days
Third-party review	No

APPLICANT

Company	**Allergan, Inc.**
Location	Walker, MI, US
Contact	PAUL S KRAMSKY
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...

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Device record: https://www.510kdatabase.net/k863201/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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