FDA 510(k) Premarket Notification

K051852 SINGLE AMPLIFIER FOR BOTOX

CLEARED

Sep 14, 2005
68 days to decision

K051852 · Product code: **GWL** · Neurology
Source: https://www.510kdatabase.net/k051852/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Jul 8, 2005
Decision date	Sep 14, 2005
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Allergan, Inc.**
Location	Walker, MI, US
Contact	SUSAN O'BRIEN
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...