

K143354 Natrelle 133 Plus Tissue ExpanderAug 20, 2015
269 days to decisionK143354 · Product code: **LCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k143354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tissue Expander And Accessories (LCJ)
Date received	Nov 24, 2014
Decision date	Aug 20, 2015
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Allergan, Inc.
Location	Walker, MI, US
Contact	Bruce Krattenmaker
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...
