FDA 510(k) Premarket Notification

K213114 BentrioTM Allergy Blocker

CLEARED

Jun 24, 2022
270 days to decision

K213114 · Product code: **NUP** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k213114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cream, Nasal, Topical, Mechanical Allergen Particle Barrier (NUP)
Date received	Sep 27, 2021
Decision date	Jun 24, 2022
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Altamira Therapeutics, Inc.**
Location	Dover, DE, US
Contact	Elena Cavallini
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**DuVal & Associates, P.A.**
Contact	Patrick Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k213114/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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