FDA 510(k) Premarket Notification

K243284 RELiZORB (100300/ 100301)

CLEARED

Jan 15, 2025
90 days to decision

K243284 · Product code: **PLQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Packed Cartridge (PLQ)
Date received	Oct 17, 2024
Decision date	Jan 15, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alcresta Therapeutics, Inc.**
Location	Newton, MA, US
Contact	Daniel Orlando
510(k) history	7 submissions · 7 cleared · 2016-2025