

K243284 RELiZORB (100300/ 100301)Jan 15, 2025
90 days to decisionK243284 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243284/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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