

K250499 RELiZORB (100300/100301)Apr 17, 2025
56 days to decisionK250499 · Product code: **PLQ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250499/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Packed Cartridge (PLQ)
Date received	Feb 20, 2025
Decision date	Apr 17, 2025
Days to decision	56 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

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