

K191379 RELIZORBDec 4, 2019
195 days to decisionK191379 · Product code: **PLQ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191379/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Packed Cartridge (PLQ) |
| Date received | May 23, 2019 |
| Decision date | Dec 4, 2019 |
| Days to decision | 195 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Alcresta Therapeutics, Inc. |
| Location | Newton, MA, US |
| Contact | Eric First |
| 510(k) history | 7 submissions · 7 cleared · 2016-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191379/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026