August 30, 2023

Alcresta Therapeutics, Inc.
℅ Matthew King
Senior Director of Regulatory Affairs
130 Turner Street, Building 3, Suite 200
Waltham, Massachusetts 02453

Re: K231156
Trade/Device Name: Enzyme Packed Cartridge - RELiZORB®
Regulation Number: 21 CFR 876.5985
Regulation Name: Enzyme Packed Cartridge
Regulatory Class: Class II
Product Code: PLQ
Dated: July 28, 2023
Received: July 31, 2023

Dear Matthew King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231156

Device Name
RELiZORB®

Indications for Use *(Describe)*
RELiZORB® is indicated for use with pediatric (ages 2 years and above) and adult patients to hydrolyze fats in enteral formula.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
(K231156)

1. General Information

Submitter Name	Alcresta Therapeutics, Inc.
Submitter Address	130 Turner Street Building 3, Suite 200 Waltham, MA 02453
FDA Establishment Owner Operator Number	10050687
FDA Establishment Registration Number/FEI	3009596666
Contact Person	Matthew King Senior Director of Regulatory Affairs Alcresta Therapeutics
Contact Information	Email: mking@alcresta.com Phone: 603-459-9755
Submission Type	Traditional 510(k)
Date Prepared	04/20/2023

2. Subject Device

Device Trade/Proprietary Name	RELiZORB®
Device Common / Regulation Name	Enzyme Packed Cartridge
Regulation Number	21 CFR 876.5985
Product Code	PLQ
Device Classification	II
Review Panel	Gastroenterology/Urology
Premarket Review	Renal, Gastrointestinal, Obesity and Transplant Devices (DHTA3A)

3. Predicate Device

Device Trade/Proprietary Name	RELiZORB®
510(k) Number	K191379
Device Common / Regulation Name	Enzyme Packed Cartridge
Regulation Number	21 CFR 876.5985
Product Code	PLQ
Device Classification	II

4. Device Description

RELiZORB® is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral feeding circuits. RELiZORB® is designed to hydrolyze (digest) fats contained in enteral formulas from triglycerides into fatty acids and monoglycerides to allow for their absorption and utilization by the body. This hydrolysis of fats by RELiZORB® is intended to mimic the function of the digestive enzyme lipase in patients who do not excrete sufficient levels of the lipase enzyme. RELiZORB® is comprised of a clear cylindrical, plastic cartridge with a single inlet connection port and a single outlet connection port. Inside the cartridge, there are small white beads that the digestive enzyme, lipase, is covalently bound to. The lipase-bead complex, iLipase™ (immobilized lipase) is retained within the cartridge during use by filters on both ends of the cartridge. The fat in enteral formulas is hydrolyzed as it comes in contact with iLipase as the formula passes through the cartridge.

5. Indications for Use

RELiZORB® is indicated for use with pediatric (ages 2 years and above) and adult patients to hydrolyze fats in enteral formula

6. Performance Data

The technological characteristics, design, materials composition, principal of operation and all other features of RELiZORB® have not changed in any manner since the clearance of K191379. Updates to the device that have taken place since the clearance of K191379 are included in this submission for the benefit of the Agency reviewers. There is no effect on the special controls applied to this product per 21 CFR 876.5985 or any of the standards to which the product was demonstrated to be in conformity with as determined in K191379.

The evidence supporting a change in the indications for use is presented in a retrospective registry study performed by Alcresta that evaluated multiple data outputs in Electronic Medical Records (EMRs) for patients between ages 2 year and 5 years to whom RELiZORB® had been prescribed to them by the This Real World Data supports the Real World Evidence that use in this use population is both safe and effective. This study and the related data analysis and conclusions have been performed in accordance with the FDA Guidance for Industry and **Food and Drug Administration Staff: Use of Real World Evidence to Support Regulatory Decision-Making for Medical Devices (August 31, 2017)**.

7. Substantial Equivalence:

The subject device is identical to the predicate device in every manner with the exception of the indications for use, which have been extended to include 2 year olds and up, where the predicate indications for use include 5 year olds and up. There have been minor updates to RELiZORB® since its last clearance for which descriptions and documentation are included in this submission to bring the current state of the device to the full attention of the Agency. The following table illustrates the identical nature of the subject and predicate devices.

Table 7.1: Subject Device to Predicate Device Comparison

Characteristics	Subject device RELiZORB	Predicate RELiZORB (K191379)
Indications for use	RELiZORB® is indicated for use in pediatric patients (ages 2 years and above) and adult patients to hydrolyze fats in enteral formula	RELiZORB® is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula
Device design	Cartridge with iLipase inside: lipase enzyme immobilized on polyacrylate beads ENFit compatible	Cartridge with iLipase inside: lipase enzyme immobilized on polyacrylate beads ENFit compatible
Principle of Operation	Hydrolyze fats in enteral formula as formula passes through the cartridge	Hydrolyze fats in enteral formula as formula passes through the cartridge
How used	Accessory that fits inline as part of enteral feeding circuit	Accessory that fits inline as part of enteral feeding circuit
Conditions of use	Single use	Single use
Flow Rate	10-120 mL/hour single cartridge 24-120 mL/hour tandem configuration	10-120 mL/hour single cartridge 24-120 mL/hour tandem configuration
Cartridge configuration in Enteral feeding set	Tandem and Single cartridge configuration (limit of 2 cartridges a day; Single cartridge for up to 500 mL; Tandem cartridge for up to 1000 mL)	Tandem and Single cartridge configuration (limit of 2 cartridges a day; Single cartridge for up to 500 mL; Tandem cartridge for up to 1000 mL)
Hydrolysis information	Hydrolysis rates for compatible enteral formulas in labeling	Hydrolysis rates for compatible enteral formulas labeling

8. Conclusion

Based on the information provided in this premarket notification to support the update to the indications for use and the demonstration that there are no differences between the subject and predicate device, RELiZORB is shown to raise no new questions of safety and efficacy and is substantially equivalent to the RELiZORB cleared in K191379.