December 21, 2023

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

Re: K232784
Trade/Device Name: RELiZORB®
Regulation Number: 21 CFR 876.5985
Regulation Name: Enzyme Packed Cartridge
Regulatory Class: Class II
Product Code: PLQ
Dated: November 17, 2023
Received: November 20, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -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)*

K232784

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."

ALCRESTA
THERAPEUTICS

510(k) SUMMARY (21 CFR 807.92)

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	September 8, 2023

2. Subject Device

Device Trade/Proprietary Name	RELiZORB®
510(k) Number	K232784
Device Common Name	Enzyme Packed Cartridge
Regulation Number	21 CFR 876.5985
Regulation Name	Enzyme Packed Cartridge
Product Code	PLQ
Device Classification	II

3. Predicate Device

Device Trade/Proprietary Name	RELiZORB®
510(k) Number	K231156
Device Common Name	Enzyme Packed Cartridge
Regulation Number	21 CFR 876.5985
Product Code	PLQ
Device Classification	II

ALCRESTA THERAPEUTICS

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. 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 covalently bonded to the digestive enzyme, lipase. This 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 upon 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. Summary of Technological Characteristics Compared to Predicate Device

The subject and predicate device have the exact same indications for use. Both devices are designed as cartridges containing lipase enzyme immobilized on polymethacrylate beads. The cartridges of the subject and predicate device are constructed of injection molded polycarbonate, with differences including new inlet and outlet filter material and design, and updates to the shape and color of the outlet fitting. The active component of the subject device, iLipase 4, consists of a Generally Accepted as Safe (GRAS) lipase preparation immobilized on a polymethacrylate bead which is under review by the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA) under Food Contact Notification (FCN) 2295 with an anticipated clearance date of October 26, 2023. The predicate iLipase uses the same bead composition and lipase enzyme cleared under FCN 1498 by CFSAN on January 20, 2015. The polymethacrylate beads used in the subject device have a larger mean diameter than the predicate device to support expanded formula compatibility. Both the subject and the predicate device use standard ENFit connectors per ISO 80369-3 for specific connection to ENFit compatible supplies for enteral feeding. The subject device was designed for connection to enteral syringes for manual bolus feeding in addition to enteral pump sets.

7. Performance Data, Special Controls, and Standards Compliance

ALCRESTA THERAPEUTICS

Performance Testing

Performance testing to support the substantial equivalence of the subject device to the predicate device in this submission include:

- Evaluation of product shelf life
- Internal and external appearance
- Pouch integrity
- Hydrolysis
- Unconjugated protein
- Microbial testing
- Physical/Mechanical Testing, including.
    - Filter tensile strength
    - Weld tensile strength
    - Filter integrity/bead retention
- Ship testing
- Biocompatibility

Preclinical Studies

Two preclinical studies were executed with the subject device in a porcine model of short bowel syndrome as assessments of safety and efficacy as well as functional performance. The first study investigated the impact of RELiZORB use during enteral feeding on fat absorption. The second study focused on the effect of bolus enteral feeding 6X per day with RELiZORB on weaning from parenteral to enteral nutrition.

Special Controls

RELiZORB is subject to special controls detailed under 21 CFR 876.5985. Each is addressed throughout this submission (summarized here):

Special Controls	Location in Submission
(1)The patient contacting components of the device must be demonstrated to be biocompatible.	Section 15
(2)In vivo testing must be performed and must demonstrate that the device causes neither an adverse tissue response nor adverse performance.	Section 19
(3) Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:	

Special Controls	Location in Submission
(i) Mechanical testing to demonstrate that the device can withstand clinical forces	Section 18
(ii) Flow rate and leakage testing to demonstrate that the device does not impede the flow of enteral formula	Section 18
(iii) Demonstration of enzymatic effect on intended macronutrient	Section 18
(iv) The amount of enzyme that exits the cartridge must be characterized	Section 10
(v) Validation that the device does not adversely impact the nutritional composition of enteral formula	Section 18
(vi) Validation that the device does not impede flow alarms on enteral feeding pumps.	Section 18 & 14
(4) Human factors testing must be performed to characterize user error risks.	Section 10
(5) Performance data must support the shelf life by demonstrating package integrity and device functionality over the identified shelf life.	Section 14
(6) Labeling must include the following:	
(i) A detailed summary of in vivo testing pertinent to use of the device, including device-related adverse events;	Section 13
(ii) A detailed summary of compatible formulas that is supported by non-clinical testing, including the expected enzymatic conversion as a percentage;	Section 13
(iii) Detailed instructions on how to place the device into an enteral feeding circuit;	Section 13
(iv) A warning regarding the possibility for misconnections; and	Section 13
(v) Expiration date or shelf life.	Section 13
(7) Patient labeling must be provided and must include:	
(i) Relevant warnings, precautions, adverse effects, and complications;	Section 13
(ii) A description of the device and how it operates;	Section 13
(iii) Instructions on how to correctly use the device; and	Section 13
(iv) The benefits and risks associated with the use of the device.	Section 13

Compliance with Standards

RELiZORB has been designed in accordance with the following standards:

- ISO 10993-1:2018, 5th Edition 2018-08
  Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2014, 3rd Edition 2014-10-01
  Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-5: 2009, 3rd Edition 2009-06-01
  Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6: 2016, 3rd Edition 2016-12-01
  Biological evaluation of medical devices- Part 6: Tests for local effects after implantation
- ISO 10993-10: 2021, 4th Edition 2021-11
  Biological evaluation of medical devices- Part 10: Tests for skin sensitization
- ISO 10993-11: 2017 Third edition 2017-09
  Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ISO 10993-12: 2021, 5th Edition 2021-01
  Biological evaluation of medical devices- Part 12: Sample preparation and reference materials
- ISO 10993-13: 2010, 2nd Edition 2010-06-15
  Biological evaluation of medical devices- Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-17: 2002, 1st Edition 2002-12-01
  Biological evaluation of medical devices- Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18: 2020, 2nd Edition 2020-01 /Amend 1 2022-05
  Biological evaluation of medical devices- Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)]
- ISO 10993-23: 2021, 1st Edition 2021-01
  Biological evaluation of medical devices- Part 23: Tests for irritation
- ISO/TR 10993-33 First Edition 2015-03-01
  Biological evaluation of medical devices- Part 33: Guidance on tests to evaluate genotoxicity – Supplement to ISO 10993-3

- ISO 80369-1: Second Edition 2018-11

Small-bore connectors for liquids and gases in healthcare applications – Part 1: General Requirements

- ISO 80369-3 First Edition 2016-07-01
  Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications (including AMMENDMENT 1 (2019)
- ISO 80369- 20: 2015 First Edition 2015-05-15
  Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common Test Methods
- ISO 20695 First Edition 2020-03
  Enteral feeding systems- Design and testing
- ISTA 3A 2018
  Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

8. Substantial Equivalence:

The subject is nearly identical to the predicate device. The subject and predicate have identical indications for use and differ only in the modifications made from the predicate to the subject to optimize performance to support expanded formula compatibility, allow for bolus feeding, and the use of 6 cartridges per day where the predicate is limited to 2 per day. The following table illustrates the substantial equivalence of the subject to the predicate.

Description	Subject device: RELiZORB (Internal project code- ALC-078)	Predicate device: RELiZORB (K231156)
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 2 years and above) and adult patients to hydrolyze fats in enteral formula.
Device design	Cartridge with iLipase 4 inside: lipase enzyme immobilized on polymethacrylate beads ENFit compatible	Cartridge with iLipase inside: lipase enzyme immobilized on polymethacrylate 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

Description	Subject device: RELiZORB (Internal project code- ALC-078)	Predicate device: RELiZORB (K231156)
How used	Cartridge that fits inline as part of enteral feeding circuit in single or tandem configuration	Cartridge that fits inline as part of enteral feeding circuit in single or tandem configuration
Conditions of use	Single use- up to 6 cartridges per day (supported by FCN 2295).	Single use- up to 2 cartridges per day (supported by FCN 1498)
Enteral feeding mode	Enteral pump; enteral syringe, (syringe push or gravity)	Enteral pump
Storage Conditions	2°C to 27°C (36°F to 80°F)	2°C to 27°C (36°F to 80°F)

9. Conclusion

Based on the information provided in this premarket notification to support modifications to the currently marketed RELiZORB to optimize performance to support expanded formula compatibility there are no significant differences between the subject and predicate device. The subject RELiZORB is shown to raise no new questions of safety and efficacy and is substantially equivalent to the RELiZORB cleared as K231156.