January 15, 2025

Alcresta Therapeutics, Inc.
Rookmin Persaud
Associate Director Regulatory Affairs
130 Turner Street
Building 3, Suite 200
Waltham, Massachusetts 02453

Re: K243284
Trade/Device Name: RELiZORB
Regulation Number: 21 CFR 876.5985
Regulation Name: Enzyme Packed Cartridge
Regulatory Class: Class II
Product Code: PLQ
Dated: October 17, 2024
Received: October 17, 2024

Dear Rookmin Persaud:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243284

Device Name

RELiZORB (100300/ 100301)

Indications for Use *(Describe)*

RELiZORB is indicated for use in pediatric (ages 1 year and above) and adults 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.

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ALCRESTA THERAPEUTICS

510(k) SUMMARY (21 CFR 807.92)

1. General Information

Submitter Name	Daniel Orlando
Submitter Address	Alcresta Therapeutics 130 Turner Street Building 3, Suite 200 Waltham, MA 02453 Phone: 847-830-6205
FDA Establishment Owner Operator Number	10050687
FDA Establishment Registration Number/FEI	3009596666
Contact Person	Rookmin Persaud Associate Director Regulatory Affairs Alcresta Therapeutics
Contact Information	Email: rpersaud@alcresta.com Phone: 732-829-7620
Submission Type	Traditional 510(k)
Date Prepared	October 17th, 2024

2. Subject Device

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

4. Device Description

RELiZORB® is a point-of-care device designed to fit in-line with currently used enteral feeding circuits. RELiZORB functions to hydrolyze (break down) fats present in enteral formulas from triglycerides into fatty acids and monoglycerides to allow for their absorption and utilization by

the body. This breakdown of fats by RELiZORB is intended to mimic the function of the enzyme pancreatic lipase. RELiZORB is comprised of a cylindrical, hollow cartridge with a single inlet

port and a single outlet port connection. Inside the cartridge, there are small white acrylic beads. The digestive enzyme, lipase, is covalently bound to the small white beads. 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 when it comes in contact with iLipase as the formula passes through the cartridge.

5. Indications for Use

RELiZORB® is indicated for use in pediatric patients (ages 1 year and above) and adult patients to hydrolyze fats in enteral formula.

6. Performance Data, Special Controls

The technological characteristics, design, material composition, principle of operation and all other features of RELiZORB have not changed in any manner since the clearance of Predicate Device K232784. Two minor updates to labeling have been implemented since the clearance of K232784 supported by test data included in reports provided in this submission; (1) the shelf-life of the device was extended to 24 months from 12 months, and (2) manual bolus enteral feeding by syringe gravity (cleared under K232784) instructions have been added to the Instructions For Use (IFU). As these changes have been implemented, Alcresta is including them to provide FDA with an update on changes to the device since the clearance of K232784. 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 K232784.

The subject of this premarket notification is an update to the Indications for Use of RELiZORB that provides the minimum age for use to 1 year old patients, currently set at 2 years old and greater. The evidence supporting this change in the Indications for Use is presented in a retrospective observational study and an evaluation of postmarket safety surveillance of RELiZORB that demonstrate device safety and effectiveness for the patient population of 1 year of age and greater. The retrospective study was performed by Alcresta and evaluated multiple data outputs in Medical Records for patients initiating RELiZORB use between ages 1 and <2 years. These Real-World Data support the Real-World Evidence that device use in this population is effective, while post-market surveillance of product complaints data supports the safety of RELiZORB in this age group. This study and the related data analysis has been designed and conducted 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)**.

ALCRESTA THERAPEUTICS

7. **Substantial Equivalence**

The subject RELiZORB is substantially equivalent to the predicate RELiZORB (K232784). An update to the Indications for Use, which have been extended to include 1-year olds and above show no new risks as supported by evidence of effectiveness based on Real World Evidence in 1 to 2 year old patients. There have been some minor updates to labeling and documents since the last clearance for which descriptions and documents 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 1. Subject to Predicate Device Comparison

Characteristics	Subject device RELiZORB	Predicate device RELiZORB (K232784)
Indications for Use	RELiZORB is indicated for use in pediatric patients (ages 1 year 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 4 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
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	Single use- up to 6 cartridges per day
Enteral feeding mode	Enteral pump; enteral syringe (syringe push or gravity)	Enteral pump; enteral syringe (syringe push or gravity)
Hydrolysis information	Hydrolysis rates for compatible enteral formulas in labeling	Hydrolysis rates for compatible enteral formulas in labeling
Storage Conditions	2°C to 27°C (36°F to 80°F)	2°C to 27°C (36°F to 80°F)

ALCRESTA THERAPEUTICS

8. Conclusion

Based on the information provided in this premarket notification to support the update to the Indications for Use and the demonstration of substantial equivalence between the subject and predicate devices, RELiZORB is shown to raise no new questions of safety and effectiveness and is substantially equivalent to RELiZORB cleared in K232784.