December 4, 2019

Alcresta Therapeutics, Inc.
Nandini Murthy
Regulatory Consultant to Alcresta
One Newton Executive Park, Suite 100
Newton, MA 02462

Re: K191379
Trade/Device Name: RELiZORB
Regulation Number: 21 CFR 876.5985
Regulation Name: Enzyme packed cartridge
Regulatory Class: II
Product Code: PLQ
Dated: November 6, 2019
Received: November 7, 2019

Dear Nandini Murthy:

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, Ph.D.
Acting 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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K191379

Device Name

RELIZORB™

Indications for Use *(Describe)*

RELiZORB™ is indicated for use with pediatric (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.

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

X Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

Submitter Name:	Alcresta Therapeutics, Inc.
Submitter Address:	One Newton Executive Park, Suite 100 Newton, MA 02462
510(k) Submission Contact:	Nandini Murthy, Regulatory Consultant
Phone Number:	781-710-5378
Sponsor Contact Person:	Dr. Eric First, CMO
Phone Number:	(617) 838-8655
Date Prepared:	11/27/2019
Device Trade Name:	RELiZORB™
Device Classification:	Class II
Classification Name:	Enzyme packed cartridge
Subject device classification	21 CFR 876.5985, Product code PLQ
Predicate Device:	RELiZORB™ DEN150001, K161247, K163057
Predicate device classification	21 CFR 876.5985, Product code PLQ
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. 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 as it comes in contact with iLipase as the formula passes through the cartridge.

Proposed Indications for Use: RELiZORB is indicated for use with pediatric (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.

Predicate Indications for Use: RELiZORB is indicated for use with pediatric (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.

Rationale for Substantial Equivalence:

Table 1- Similarities between Subject device to FDA-Cleared RELiZORB:

Characteristics	Subject device RELiZORB	FDA-cleared RELiZORB DEN150001, K161247, K163057
Indications for use	RELiZORB is indicated for use in pediatric patients (ages 5 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 bead 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

Characteristics	Subject device RELiZORB	FDA-cleared RELiZORB DEN150001, K161247, K163057
Conditions of use	Single use	Single use

Table 2 - Minor Differences between Subject device to FDA-Cleared RELiZORB:

Characteristics	Subject device RELiZORB	FDA-cleared RELiZORB DEN150001, K161247, K163057
Flow Rate	10-120 mL/hour single cartridge 48-120 mL/hour tandem configuration	24-120 mL/hour single cartridge
Cartridge instructions for use (optional tandem)	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)	Single cartridge configuration (limit of 2 cartridges a day; 1 cartridge for up to 500 mL)
Optional Pause time during use	15 minutes (up to 1 hour)	15 minutes
Primary pouch	5.24” x 5.50”	8.00” x 4.48”
Manufacturing process	Weld process parameter update, with minor changes to cartridge to improve yield (no change to method for attaching components)	Welded interface in cartridge
Filters	Inlet and Outlet filter configuration & inspection instructions updated. No change to materials, functional specifications, placement, manufacturing method of filter	Includes Inlet and Outlet filters
iLipase beads	Small change in median range for bead size, density characteristics. No change in placement, functional specifications	iLipase beads in cartridge

Alcresta Therapeutics, Inc.
RELiZORB 510(k) K191379

Section 5 – 510(k) Summary

Performance data: The following test reports were included to demonstrate equivalence:

Pouch seal/tensile/visual testing
Primary pouch ship testing (ISTA 2A: Packaged-Products weighing 150 lb (68 kg) or less. Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing)
Filter integrity performance
Hydrolysis
Flow rate
Leak testing

Standards: All prior testing with the predicate RELiZORB device (DEN150001, K161247, K161247/A001) to the following standards are unaffected.

- EN 62366:2008 Medical devices – Application of usability engineering to medical devices.
- EN ISO 14971:2012 – Medical devices. Application of risk management.
- ISO-14644: Cleanrooms and associated controlled environments and associated controlled environments.
- ISO / FDIS 80369-3 First Edition 2016-04-25, Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 3: Connectors For Enteral Applications

Substantial Equivalence rationale:

The Indications for Use is identical to the predicate. There are no changes to target population or intended use.

Indications for Use:

RELiZORB is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula

Technology & Design:

The materials of construction, size, instructions for use (including connection instructions, limit of 2 cartridges/day, use of 1 cartridge/500 mL of enteral formula) between the subject and predicate devices are equivalent. Minor differences noted in Table 2 above do not raise new

questions of safety and effectiveness. Where changes required verification or validation testing, such testing was conducted to confirm equivalence.

Test Results:

All Non-Clinical test results show that the subject RELiZORB is equivalent to the predicate RELiZORB.

Substantial Equivalence Conclusion:

The subject RELiZORB is equivalent to the predicate RELiZORB.