DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 12, 2017

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

Re: K163057
Trade/Device Name: RELiZORB
Regulation Number: 21 CFR§ 876.5985
Regulation Name: Enzyme Packed Cartridge
Regulatory Class: II
Product Code: PLQ
Dated: June 8, 2017
Received: June 12, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*

K163057

Device Name

RELiZORB™

Indications for Use *(Describe)*

RELiZORB™ is indicated for use in pediatric patients (ages 5 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)

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: Eric First, CSO

Phone Number: 732-926-4823

Date Prepared: 07/06/2017

Device Trade Name: RELiZORB™

Device Common Name: Enzyme Packed Cartridge

Subject device classification 21 CFR 876.5985, Product code PLQ

Predicate Device: RELiZORB™ DEN150001, K161247, K161247/A001

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 in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.

Predicate Indications for Use: RELiZORB is indicated for use in adults to hydrolyze fats in enteral formula.

Purpose of Submission: To change the indicated patient population to include pediatric patients and to update the shelf life.

Rationale for Substantial Equivalence:

Table 1:Comparison of RELiZORB to the Predicate Device

Characteristics	Subject device: RELiZORB	Predicate device: RELiZORB (DEN150001), K161247, K161247/A001
Indications for use	Indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula	Indicated for use in adults to hydrolyze fats in enteral formula
Device design	Cartridge with beads inside, with lipase enzyme immobilized on these beads ENFit compatible	Cartridge with beads inside, with lipase enzyme immobilized on these beads ENFit compatible
Principle of Operation	Hydrolyze fats in enteral formula as formula passes through the	Hydrolyze fats in enteral formula as formula passes through the

Alcresta Therapeutics, Inc.
RELiZORB Traditional 510(k) K163057

Section 5 – 510(k) Summary

Characteristics	Subject device: RELiZORB	Predicate device: RELiZORB (DEN150001), K161247, K161247/A001
	cartridge	cartridge
How used	Accessory that fits in-line as part of enteral feeding circuit	Accessory that fits in-line as part of enteral feeding circuit
Conditions of use	Single use	Single use

Performance Data: The following RELiZORB performance testing was performed to support this 510(k) submission:

Shelf life testing: The following tests were performed as part of shelf life

- Tensile and mechanical strength
- Flow rate
- Hydrolysis
- Microbiological testing

Clinical testing:
To support the proposed labeling update in this 510(k), Alcresta completed a multicenter, randomized, double-blind, placebo-controlled crossover clinical study in adult and pediatric patients with cystic fibrosis (CF) receiving enteral feeding. Patients with CF have known fatty acid deficiencies and are the most representative pediatric population with fat malabsorption using enteral nutrition. The duration of the study was 27 days. The purpose was to evaluate the safety, tolerability (evaluated through analysis of gastrointestinal (GI) symptoms and select activities of daily living), and fat absorption with use of RELiZORB as a part of the enteral feeding circuit in patients with CF who have confirmed exocrine pancreatic insufficiency (EPI).

Thirty-five (35) patients were enrolled in the study; two patients withdrew from the study prior to exposure to RELiZORB (one unrelated health issue and one where study procedure was not followed). Thirty-three (33) evaluable patients completed the study. Both GI symptoms and non-GI adverse events were captured during the study. The most commonly

reported GI events were abdominal pain, gas and bloating, while the most common non-gastrointestinal adverse event reported was headache. RELiZORB use during administration of enteral nutrition in pediatric and adult subjects with CF resulted in a 2.8-fold change in plasma concentrations of physiologically relevant long-chain polyunsaturated fatty acids (LCPUFAs) such as DHA and EPA (biomarkers of fat absorption), as measured by plasma absorption kinetics and bioavailability profile, represented by the area under the concentration time curve (AUC). In addition, there was a 2.1-fold change in peak plasma concentrations (C_{max}) of DHA and EPA. These results confirm the absorption of DHA and EPA previously demonstrated in the porcine model (predicate RELiZORB).

Conclusion:
Shelf life test results support labeled shelf life of RELiZORB.

The clinical study results support the proposed indications for use for RELiZORB to include use in pediatric patients (ages 5 years and above). There are no changes to device design, technology or functionality. Both adults and pediatric patients consume similar volumes of enteral formulas, ingest similar amounts of fat and use similar doses of PERT. Enteral formulas used by pediatric and adult patients are comparable in composition. Therefore, there have been no changes in warnings or instructions for use of the device, other than those associated with the proposed update to the indications for use of this 510(k). The subject RELiZORB is substantially equivalent to the predicate RELiZORB device.