



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

June 30, 2016

Alcresta Therapeutics, Inc.  
Nandini Murthy  
Regulatory Consultant to Alcresta  
One Newton Executive Park, Suite 102  
Newton, MA 02462

Re: K161247  
Trade/Device Name: RELIZORB™  
Regulation Number: 21 CFR §876.5985  
Regulation Name: Enzyme Packed Cartridge  
Regulatory Class: II  
Product Code: PLQ  
Dated: April 29, 2016  
Received: May 3, 2016

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 yours,

  
**Benjamin R. Fisher -S**

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

## Indications for Use

510(k) Number (if known)

K161247

Device Name

RELiZORB™

Indications for Use (Describe)

RELiZORB™ is indicated for use in adults 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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**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:** Robert Gallotto, President and COO

**Phone Number:** 617-431-3600

**Date Prepared:** 30 June, 2016

**Device Trade Name:** RELiZORB™

**Device Common Name:** Enzyme Packed Cartridge

**Subject device classification** 21 CFR 876.5985, Product code PLQ

**Predicate Device:** RELiZORB™, DEN150001

**Predicate device classification** 21 CFR 876.5985, Product code PLQ

**Device Description:** The RELiZORB device is a point-of-care accessory designed to fit in line with currently used enteral feeding circuits. RELiZORB is designed 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 the RELiZORB is intended to mimic the function of the enzyme lipase in patients who do not excrete sufficient levels of 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 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.

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

**Rationale for Substantial Equivalence:**

<b>Characteristics</b>	Subject device: RELiZORB	Predicate device: RELiZORB (DEN150001)
<b>Indications for use</b>	indicated for use in adults to hydrolyze fats in enteral formula	indicated for use in adults to hydrolyze fats in enteral formula
<b>Device design</b>	Cartridge with beads inside, with lipase enzyme immobilized on these beads	Cartridge with beads inside, with lipase enzyme immobilized on these beads
<b>Principle of Operation</b>	Hydrolyze fats in enteral formula as formula passes through the cartridge	Hydrolyze fats in enteral formula as formula passes through the cartridge
<b>How used</b>	Accessory that fits inline as part of enteral feeding circuit	Accessory that fits inline as part of enteral feeding circuit
<b>Conditions of use</b>	Single use	Single use

**Table 1: Comparison of RELiZORB to the Predicate Device**

**Performance Data:** Shelf life testing of RELiZORB was completed and met the acceptance criteria in the protocol. The shelf life test results support the proposed edit to the labeling with respect to product stability.

The RELiZORB device was previously tested to demonstrate that the device performs as intended under anticipated conditions of use, and safety, including:

- Tensile and mechanical strength
- Flow rate
- Demonstration of enzymatic effect on macronutrients
- Impurities/degradants characterization
- Animal testing to demonstrate hydrolysis effect
- Human factors testing

RELiZORB testing was done per design control requirements of 21 CFR Part 820. The Risk management file was reviewed and there was no significant change to the risk assessment as a result of the proposed minor change to the labeling.

Alcresta develops and manufactures RELiZORB in compliance with the Quality System regulations (21 CFR 820).

**Standards:** There were no standards that were applicable to the shelf life testing conducted. All prior testing with the predicate RELiZORB device (DEN150001) to the following standards are unaffected by the proposed labeling change.

- ISO 10993-1:2009/Cor 1:2010 - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- EN 62366:2008 Medical devices – Application of usability engineering to medical devices
- EN ISO 14971:2012 – Medical devices. Application of risk management.
- ISTA 2A: Packaged-Products weighing 150 lb (68 kg) or Less. Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing.
- AAMI/ANSI ID54: 1996/(R)2012: Enteral feeding set adapters and connectors
- ISO-14644: Cleanrooms and associated controlled environments and associated controlled environments

**Conclusion:**

The subject RELiZORB has the same indications for use as the predicate device. There have been no changes in warnings or instructions for use of the device. There are no changes to device design, technology or functionality. Therefore the subject RELiZORB is substantially equivalent to the predicate RELiZORB device.