



April 12, 2019

Gelesis, Inc.  
% Debbie Koeneman  
Consultant  
NDA Partners, LLC  
40 Commerce Lane, Suite D  
Rochelle, Virginia 22738

Re: DEN180060

Trade/Device Name: Plenity

Regulation Number: 21 CFR 876.5982

Regulation Name: Ingested, transient, space occupying device for weight management and/or weight loss

Regulatory Class: Class II

Product Code: QFQ

Dated: November 12, 2018

Received: November 15, 2018

Dear Debbie Koeneman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of Plenity, a prescription device under 21 CFR Part 801.109 with the following indications for use:

Plenity is indicated to aid in weight management in overweight and obese adults with a Body Mass Index (BMI) of 25 - 40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies Plenity, and substantially equivalent devices of this generic type, into Class II under the generic name ingested, transient, space occupying device for weight management and/or weight loss.

FDA identifies this generic type of device as:

**Ingested, transient, space occupying device for weight management and/or weight loss.** This device is an ingested material that transiently occupies space in the stomach. The device passes from the body via the natural gastrointestinal tract.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 15, 2018, FDA received your De Novo requesting classification of Plenity. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify Plenity into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, Plenity can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Device related gastrointestinal adverse events, including: <ul style="list-style-type: none"> <li>• Obstruction</li> <li>• Dilation</li> <li>• Diarrhea</li> <li>• Constipation</li> <li>• Dehydration</li> </ul>	Clinical performance testing Non-clinical performance testing Labeling Shelf life testing
Weight gain	Clinical performance testing Labeling
Interaction with medication	Clinical performance testing Non-clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection	Non-clinical performance testing Shelf life testing

In combination with the general controls of the FD&C Act, the ingested, transient, space occupying device for weight management and/or weight loss is subject to the following special controls:

- (1) The patient-contacting components of the device must be demonstrated to be biocompatible for its intended use.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

- (i) Performance bench testing in a simulated use model must evaluate device disintegration and device hydration state throughout the gastrointestinal tract.
  - (ii) Bioburden and moisture content assessments must evaluate device infection risk throughout the labeled shelf life.
  - (iii) Performance data must support the shelf life of the device by demonstrating continued package integrity and device functionality over the labeled shelf life.
- (3) Clinical performance testing must demonstrate the device performs as intended and evaluate the following:
- (i) Weight change;
  - (ii) All adverse events, including obstruction, dilation, diarrhea, constipation, and dehydration; and
  - (iii) Interaction with representative medications.
- (4) Physician and patient device labeling must state:
- (i) The clinical benefit of the device as assessed by using percent total body weight loss;
  - (ii) Treatment must be offered in combination with diet and exercise;
  - (iii) Instructions on how to use the device as intended including how to avoid interaction with medication; and
  - (iv) The shelf life of the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CDRHProductJurisdiction@fda.hhs.gov](mailto:CDRHProductJurisdiction@fda.hhs.gov).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the ingested, transient, space occupying device for weight management and/or weight loss they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact April Marrone at 240-402-6510.

Sincerely,

Angela C. Krueger  
Deputy Director, Engineering and Science Review  
Office of Device Evaluation  
Center for Devices and Radiological Health