nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, the collections of information in part 820 have been approved under OMB control number 0910–0073, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 866.2190 to subpart C to read as follows:

§ 866.2190 Automated image assessment system for microbial colonies on solid culture media.

(a) *Identification.* An automated image assessment system for microbial colonies on solid culture media is a system that is intended to assess the presence or absence of microbial colonies on solid microbiological culture medium, and to interpret their number, and phenotypic and morphologic characteristics through analysis of two dimensional digital images as an aid in diagnosis of infectious disease.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Premarket notification submissions must include a detailed description of the device, including the technology employed, components and software modules, as well as a detailed explanation of the result algorithms and any expert rules that are used to assess colony characteristics and enumerate colonies from image capture through end result.

(2) Premarket notification submissions must include detailed documentation of the analytical studies performed to characterize device performance to support the intended use, as appropriate.

(3) Premarket notification submissions must include detailed documentation from clinical studies performed on a population that is consistent with the intended use population.

(i) The clinical studies must establish the device performance based on comparison to results obtained by an acceptable reference method, as appropriate.

(ii) The clinical study documentation must include the study protocol with a predefined statistical analysis plan and the final report documenting support for the Indications for Use and the results of the statistical analysis, as appropriate.

(4) Premarket notification submissions must include detailed documentation for device software, including but not limited to software applications and hardware based components that incorporate software, and any decision-making thresholds used to generate results for the device. If a part of a Total Laboratory Automation System, the premarket notification submission must include detailed documentation addressing the instrument and software system integration.

(5) Premarket notification submissions must include detailed documentation of appropriate instructions for use regarding the intended user's device quality control procedures for the instrument system and components, as appropriate.

(6) The 21 CFR 809.10 compliant device labeling must include:

(i) Detailed user instructions to mitigate the risk of failure to operate the instrument correctly.

(ii) A detailed explanation of the interpretation of results and limitations regarding the need for review of culture plates by a qualified microbiologist, as appropriate.

(iii) A summary of performance data obtained from the analytical studies used to support device performance, as appropriate.

(iv) A summary of performance data obtained from clinical studies performed on a population that is consistent with the intended use population, as appropriate.

(7) Under 21 CFR 820.30 compliant design control, device manufacturers must, as appropriate:

(i) Conduct human factors/usability validation testing with the final version of the labeling and related materials to adequately mitigate the risk of failure to operate the instrument correctly.

(ii) Document a device training program that will be offered to the end user to adequately mitigate the risk of failure to operate the instrument correctly.

Dated: October 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–22305 Filed 10–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2017–N–5224]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Enzyme Packed Cartridge

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the enzyme packed cartridge into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the enzyme packed cartridge's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 16, 2017. The classification was applicable on November 20, 2015.

FOR FURTHER INFORMATION CONTACT: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD, 20993–0002, 301–796–5155, *joshua.silverstein@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the enzyme packed cartridge as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In

addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On January 2, 2015, Alcresta, Inc. submitted a request for De Novo classification of the RELIZORB™. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 20, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5985. We have named the generic type of device enzyme packed cartridge, and it is identified as an *ex vivo* prescription device that is used in enzymatic hydrolysis of macronutrients into their essential nutrient forms at the time of delivery. The device consists of an outer casing containing an inert polymer with a covalently bound enzyme through which nutritional formula is directed. The device fits in line with enteral feeding systems.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ENZYME PACKED CARTRIDGE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility testing, Non-clinical testing, *In vivo* testing, and Labeling.
Mechanical failure • Deprivation of care. • Device clogging. • Filter becomes dislodged and releases beads into enteral formula.	Non-clinical testing, Shelf life testing, and Labeling.
Reduced enzymatic effect	Non-clinical testing, *In vivo* testing, Shelf life testing, and Labeling.
Use error	Human factors testing and Labeling.
Infection	Shelf life testing and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this

final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

At the time of classification, enzyme packed cartridges are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 876.5985 to subpart F to read as follows:

§ 876.5985 Enzyme packed cartridge.

(a) *Identification.* An enzyme packed cartridge is an *ex vivo* prescription device that is used in enzymatic hydrolysis of macronutrients into their essential nutrient forms at the time of delivery. The device consists of an outer casing containing an inert polymer with a covalently bound enzyme through which nutritional formula is directed. The device fits in line with enteral feeding systems.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting components of the device must be demonstrated to be biocompatible.

(2) *In vivo* testing must be performed and must demonstrate that the device causes neither an adverse tissue response nor adverse performance.

(3) Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mechanical testing to demonstrate that the device can withstand clinical forces;

(ii) Flow rate and leakage testing to demonstrate that the device does not impede the flow of enteral formula;

(iii) Demonstration of enzymatic effect on intended macronutrient;

(iv) The amount of enzyme that exits the cartridge must be characterized;

(v) Validation that the device does not adversely impact the nutritional composition of enteral formula; and

(vi) Validation that the device does not impede flow alarms on enteral feeding pumps.

(4) Human factors testing must be performed to characterize use error risks.

(5) Performance data must support shelf life by demonstrating package integrity and device functionality over the identified shelf life.

(6) Labeling must include the following:

(i) A detailed summary of *in vivo* testing pertinent to use of the device, including device-related adverse events;

(ii) A detailed summary of compatible formulas that is supported by non-clinical testing, including the expected enzymatic conversion as a percentage;

(iii) Detailed instructions on how to place the device into an enteral feeding circuit;

(iv) A warning regarding the possibility for misconnections; and

(v) Expiration date or shelf life.

(7) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, adverse effects, and complications;

(ii) A description of the device and how it operates;

(iii) Instructions on how to correctly use the device; and

(iv) The benefits and risks associated with the use of the device.

Dated: October 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22286 Filed 10–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–402]

Schedules of Controlled Substances: Placement of AB-CHMINACA, AB-PINACA and THJ-2201 Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA), and [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This rule continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle AB-CHMINACA, AB-PINACA and THJ-2201.

DATES: Effective October 16, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its