CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because this guidance sets out compliance policy that reduces burden and is consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

Before 2016, FDA regulations did not define the term ''dietary fiber'' for purposes of the Nutrition Facts and Supplement Facts labels. In the **Federal Register** of May 27, 2016 (81 FR 33742), we published a final rule amending our Nutrition Facts and Supplement Facts Labels regulations (hereafter referred to as ''the final rule''). The final rule, among other things, defines dietary fiber as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health (§ 101.9(c)(6)(i) (21 CFR 101.9(c)(6)(i))). The final rule also identifies seven isolated or synthetic non-digestible carbohydrates, each of which has a physiological effect that is beneficial to human health and that must be declared as dietary fiber on Nutrition and Supplement Facts labels when present in a food.

Interested parties can ask us to list additional isolated or synthetic non-digestible carbohydrates in the definition of dietary fiber in § 101.9(c)(6)(i). For example, a manufacturer can request FDA to include another added isolated or synthetic non-digestible carbohydrate in the listing of dietary fibers by submitting a citizen petition under 21 CFR 10.30. FDA would review the scientific evidence to determine whether the evidence supports the non-digestible carbohydrate as having a physiological effect that is beneficial to human health. If so, FDA would propose a rule to include the non-digestible carbohydrate in the listing of dietary fibers.

Based on our review of citizen petitions that FDA has received requesting that we identify additional isolated or synthetic non-digestible carbohydrates in the listing of dietary fibers, and comments that we have received on a draft guidance entitled ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)'' and an accompanying document titled ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates,'' the availability of which we announced in the **Federal Register** of November 23, 2016 (81 FR 84516 and 81 FR 84595), in addition to our independent evaluation of the available scientific data, we intend to add certain isolated or synthetic non-digestible carbohydrates to the dietary fiber definition in § 101.9(c)(6)(i) through our regular rulemaking process. The eight non-digestible carbohydrates that we intend to add are: Mixed plant cell wall fibers; arabinoxylan; alginate, inulin and inulin-type fructans; high amylose starch (resistant starch 2); galactooligosaccharide; polydextrose; and resistant maltodextrin/dextrin. One category of non-digestible carbohydrate that we intend to add to § 101.9(c)(6)(i) through our regular rulemaking process—mixed plant cell wall fibers—encompasses a number of fiber ingredients, such as rice bran fibers, soy fibers, and sugar cane fibers. We have tentatively determined that each of these isolated or synthetic non-digestible carbohydrates has a physiological effect that is beneficial to human health. Several petitions are still pending with FDA and reviewing this information is a very high priority for FDA. Firms also can submit new citizen petitions, and we will review the petitions on a rolling basis. Firms whose non-digestible carbohydrates do not meet our regulatory definition of ''dietary fiber'' and are not one of the eight non-digestible carbohydrates identified in the guidance can still use those non-digestible carbohydrates in foods. Although those non-digestible carbohydrates cannot be listed as dietary fiber in the Nutrition Facts label, they would still be declared as part of the amount of total carbohydrate and listed by name in the ingredients on the food package. In addition, based on our review of the scientific evidence, including evidence we received in a citizen petition, we intend to establish a caloric value for polydextrose at 1 kcal/g in § 101.9(c)(1)(i)(C).

Pending completion of the rulemaking process, we are announcing a policy for the eight identified isolated or synthetic non-digestible carbohydrates when one or more are present in food and declared in the amount of ''dietary fiber'' on Nutrition Facts and Supplement Facts labels and when the caloric value of 1 kcal/g is used to determine the calorie contribution of polydextrose. Section 101.9(g) requires manufacturers to make and keep records to verify the amount of non-digestible carbohydrates added to food that do not meet the definition of dietary fiber. Under our policy, when a mixture of dietary fiber and one or more of these eight added non-digestible carbohydrates (that are not currently listed as a ''dietary fiber'' in the definition in § 101.9(c)(6)(i)) are present in a food, we do not expect manufacturers to make and keep records in accordance with § 101.9(g)(10) and (11) to verify the declared amount of one or more of these eight added non-digestible carbohydrates in the label and labeling of food.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12867 Filed 6–14–18; 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–2018–N–1894]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Fluid Jet System for Prostate Tissue Removal

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the fluid jet system for prostate tissue removal 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 fluid jet

system for prostate tissue removal'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 June 15, 2018. The classification was applicable on December 21, 2017.

FOR FURTHER INFORMATION CONTACT: Jessica Cades, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G246, Silver Spring, MD, 20993–0002, 240–402–3900, *Jessica.Cades@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the fluid jet system for prostate tissue removal 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 (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 (21 U.S.C. 360(k) and part 807 (21 CFR part 807).

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 (21 U.S.C. 360c(f)(2)). 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 PMA 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 April 17, 2017, PROCEPT BioRobotics Inc. submitted a request for De Novo classification of the AQUABEAM System. 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 the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 21, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.4350. We have named the generic type of device fluid jet system for prostate tissue removal, and it is identified as a prescription device intended for the resection and removal of prostatic tissue for the treatment of benign prostatic hyperplasia. The device cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra. The device is able to image the treatment area, or pairs with an imaging modality, to monitor treatment progress.

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—FLUID JET SYSTEM FOR PROSTATE TISSUE REMOVAL RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Injury from device operation causing one or more of the following: • Bleeding • Bruising • Penile or pelvic pain	Clinical performance testing, Animal testing, Labeling, and Training.

TABLE 1—FLUID JET SYSTEM FOR PROSTATE TISSUE REMOVAL RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
• Dysuria • Incontinence • Bladder or prostate capsule perforation • Sexual dysfunction, including ejaculatory and erectile dysfunction • Transurethral resection syndrome • Urethral damage causing false passage or stricture • Rectal incontinence/perforation • Embolism	
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation, Reprocessing validation, Shelf life testing, and Labeling.
Failure to remove target tissue or removal of non-target tissue	Clinical performance testing, Animal testing, Software verification, validation, and hazard analysis, Non-clinical performance testing, Labeling, and Training.
Electrical shock or electromagnetic interference	Electrical safety testing, Electromagnetic compatibility 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. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, fluid jet systems for prostate tissue removal 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 and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

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 order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; 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 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 § 876.4350 to subpart E to read as follows:

§ 876.4350 Fluid jet system for prostate tissue removal.

(a) *Identification.* A fluid jet system for prostate tissue removal is a prescription device intended for the resection and removal of prostatic tissue for the treatment of benign prostatic hyperplasia. The device cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra. The device is able to image the treatment area, or pairs with an imaging modality, to monitor treatment progress.

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

(1) Clinical performance testing must evaluate the following:

(i) All adverse events associated with the device, and

(ii) Improvement in lower urinary tract symptoms (LUTS).

(2) Physician training must be provided that includes:

(i) Information on key aspects and use of the device, and

(ii) Information on how to override or stop resection.

(3) Animal testing must demonstrate that the device resects targeted tissue in a controlled manner without injury to adjacent non-target tissues.

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

(i) Measurement of targeting accuracy and reproducibility of high velocity fluid jet, and

(ii) High pressure fluid jet verification testing at target and non-target tissues.

(5) Software verification, validation, and hazard analysis must be performed.

(6) The patient-contacting elements of the device must be demonstrated to be biocompatible.

(7) Performance data must demonstrate the electrical safety and electromagnetic compatibility of the device.

(8) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(9) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(10) Performance data must validate the instructions for reprocessing and reliability of reusable components.

(11) Labeling must include the following:

(i) A section that summarizes the clinical testing results, including the adverse event profile and improvement in LUTS;

(ii) A shelf life for single use components;

(iii) A use life for reusable components; and

(iv) Reprocessing instructions for reusable components.

Dated: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12829 Filed 6–14–18; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Allocation of Assets in Single-Employer Plans; Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under the benefit payments regulation for valuation dates in July 2018 and interest assumptions under the asset allocation regulation for valuation dates in the third quarter of 2018. The interest assumptions are used for valuing and paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective July 1, 2018.

FOR FURTHER INFORMATION CONTACT: Hilary Duke (*duke.hilary@PBGC.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–326–4400, ext. 3839. (TTY users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 202–326–4400, ext. 3839.)

SUPPLEMENTARY INFORMATION: PBGC's regulations on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) and Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumptions in the regulations are also published on PBGC's website (*http://www.pbgc.gov*).

The interest assumptions in appendix B to part 4044 are used to value benefits for allocation purposes under ERISA section 4044. PBGC uses the interest assumptions in appendix B to part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the asset allocation regulation are updated quarterly; assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for July 2018 and updates the asset allocation interest assumptions for the third quarter (July through September) of 2018.

The third quarter 2018 interest assumptions under the allocation regulation will be 2.53 percent for the first 25 years following the valuation date and 2.64 percent thereafter. In comparison with the interest assumptions in effect for the second quarter of 2018, these interest assumptions represent an increase of 5 years in the select period (the period during which the select rate (the initial rate) applies), an increase of 0.26 percent in the select rate, and an increase of 0.05 percent in the ultimate rate (the final rate).

The July 2018 interest assumptions under the benefit payments regulation will be 1.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for June 2018, these interest assumptions represent no change in the immediate rate and no changes in i1, i2, or i3.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits under plans with valuation dates during July 2018, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 297 is added at the end of the table to read as follows:

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *