17 CFR Part 230

Reporting and recordkeeping requirements, Securities.

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 227 is revised to read as follows:

Authority: 15 U.S.C. 77d, 77d–1, 77s, 77z–3, 78c, 78o, 78q, 78w, 78mm, and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

■ 2. Amend § 227.202 by adding paragraph (c) to read as follows:

§ 227.202 Ongoing reporting requirements.

* * * * *

(c) *Temporary relief from certain reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by this section (Rule 202), Rule 203(a)(3) (§ 227.203(a)(3)), or Rule 203(b) (§ 227.203(b)), as applicable:

(i) During the period from and including August 25, 2017 to and including October 26, 2017 due to Hurricane Harvey and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before October 27, 2017;

(ii) During the period from and including September 6, 2017 to and including November 7, 2017 due to Hurricane Irma and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 8, 2017; or

(ii) During the period from and including September 20, 2017 to and including November 21, 2017 due to Hurricane Maria and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 22, 2017.

(2) In any report or form filed pursuant to paragraph (c)(1) of this section, the issuer must disclose that it is relying on this paragraph (c) (Rule 202(c) of Regulation Crowdfunding) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

■ 4. Amend § 230.257 by adding paragraph (f) to read as follows:

§ 230.257 Periodic and current reporting; exit report.

* * * * *

(f) *Temporary relief from ongoing reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by Rule 252(f)(2)(i) (§ 230.252(f)(2)(i)) or this section (Rule 257), as applicable:

(i) During the period from and including August 25, 2017 to and including October 26, 2017 due to Hurricane Harvey and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before October 27, 2017;

(ii) During the period from and including September 6, 2017 to and including November 7, 2017 due to Hurricane Irma and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 8, 2017; or

(ii) During the period from and including September 20, 2017 to and including November 21, 2017 due to Hurricane Maria and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 22, 2017.

(2) In any report or form filed pursuant to paragraph (f)(1) of this section, the issuer must disclose that it is relying on this paragraph (f) (Rule 257(f) of Regulation A) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

By the Commission.

Dated: September 27, 2017.

Brent J. Fields,

Secretary.

[FR Doc. 2017–21094 Filed 9–28–17; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2017–N–5153]

Medical Devices; Gastroenterology-Urology Devices; Classification of the High Intensity Ultrasound System for Prostate Tissue Ablation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the high intensity ultrasound system for prostate tissue ablation 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 high intensity ultrasound system for prostate tissue ablation'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 2, 2017. The classification was applicable on October 9, 2015.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G210, Silver Spring, MD 20993–0002, 301–796–6549, *john.baxley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the high intensity ultrasound system for prostate tissue ablation 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 March 23, 2015, SonaCare Medical, LLC submitted a request for De Novo classification of the Sonablate® 450. 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 October 9, 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 876.4340. We have named the generic type of device high intensity ultrasound system for prostate tissue ablation, and it is identified as a prescription device that transmits high intensity therapeutic ultrasound energy into the prostate to thermally ablate a defined, targeted volume of tissue, performed under imaging guidance. This classification does not include devices that are intended for the treatment of any specific prostate disease and does not include devices that are intended to ablate non-prostatic tissues/organs.

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—HIGH INTENSITY ULTRASOUND SYSTEM FOR PROSTATE TISSUE ABLATION RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Thermal injury from high intensity ultrasound exposure to non-target tissue: • Erectile dysfunction • Urinary incontinence • Rectal fistula • Osteomyelitis pubis	Non-clinical performance testing; Software verification, validation, and hazard analysis; *In vivo* testing; Clinical testing; Labeling; and Physician training.
Thermal injury from high intensity ultrasound exposure to target tissue: • Urethral stricture • Bladder neck contracture • Urinary retention • Tissue debris/obstruction • Voiding dysfunction • Dysuria • Hematuria • Ejaculation disorder	Clinical testing, Labeling, and Physician training.
Mechanical injury from unintentional movement of ultrasound components: • Patient rectal injury • Operator hand injury	Software verification, validation, and hazard analysis; Clinical testing; Labeling; and Physician training.

TABLE 1—HIGH INTENSITY ULTRASOUND SYSTEM FOR PROSTATE TISSUE ABLATION RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Infection	Sterilization validation, Reprocessing validation, Shelf life validation, and Labeling.
Electrical shock/electromagnetic interference	Electrical safety testing, Electromagnetic compatibility testing, and Labeling.
Adverse tissue reaction	Biocompatibility testing.

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, high intensity ultrasound systems for prostate tissue ablation 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 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, 360l, 371.

■ 2. Add § 876.4340 to subpart E to read as follows:

§ 876.4340 High intensity ultrasound system for prostate tissue ablation.

(a) *Identification.* A high intensity ultrasound system for prostate tissue ablation is a prescription device that transmits high intensity therapeutic ultrasound energy into the prostate to thermally ablate a defined, targeted volume of tissue, performed under imaging guidance. This classification does not include devices that are intended for the treatment of any specific prostate disease and does not include devices that are intended to ablate non-prostatic tissues/organs.

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

(1) 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) Characterization of acoustic pressure and power output at clinically relevant levels;

(ii) Measurement of targeting accuracy and reproducibility of high intensity ultrasound output;

(iii) Ultrasound-induced heating verification testing at target and non-target tissues;

(iv) Electrical safety testing; and

(v) Electromagnetic compatibility testing.

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

(3) The elements of the device that may contact the patient's mucosal tissue must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that contact the patient's mucosal tissue.

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

(6) Performance data must support the instructions for reprocessing all reusable components.

(7) *In vivo* testing must demonstrate that the device thermally ablates targeted tissue in a controlled manner without thermal injury to adjacent, non-target tissues.

(8) Clinical testing must document the adverse event profile, provide evidence of prostatic ablation, and demonstrate that the device performs as intended under anticipated conditions of use.

(9) Training must be provided so that upon completion of the training program, the physician can:

(i) Use all safety features of the device;

(ii) Accurately target the high intensity ultrasound energy within the desired region of the prostate; and

(iii) Perform the ablation procedure in a manner that minimizes damage to non-target tissues.

(10) Labeling must include:

(i) A section that summarizes the clinical testing results, including the adverse event profile and evidence of prostate ablation achieved; and

(ii) An expiration date or shelf life for single use components.

Dated: September 25, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–21074 Filed 9–29–17; 8:45 am]

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