



Food and Drug Administration
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October 9, 2015

SonaCare Medical, LLC
Dawn Burleson, RN, MBA, CCRA
Vice President of Clinical Affairs
10130 Perimeter Parkway, Suite 250
Charlotte, NC 28216

Re: DEN150011
Sonablate[®] 450
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.4340
Regulation Name: High intensity ultrasound system for prostate tissue ablation
Regulatory Classification: Class II
Product Code: PLP
Dated: March 23, 2015
Received: March 24, 2015

Dear Dawn Burleson:

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 the Sonablate[®] 450, a prescription device under 21 CFR Part 801.109 that is *indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostatic tissue*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Sonablate[®] 450, and substantially equivalent devices of this generic type, into class II under the generic name, high intensity ultrasound system for prostate tissue ablation.

FDA identifies this generic type of device as:

High intensity ultrasound system for prostate tissue ablation. A high intensity ultrasound system for prostate tissue ablation is a prescription device that transmits high intensity therapeutic ultrasound (HITU) 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.

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1)

of the Act. 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** classifying the device type.

On March 24, 2015, FDA received your *de novo* requesting classification of the Sonablate® 450 into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Sonablate® 450 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 the Sonablate® 450 indicated for *transrectal high intensity focused ultrasound (HIFU) ablation of prostatic tissue* 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Thermal injury from high intensity ultrasound exposure to non-target tissue: -erectile dysfunction -urinary incontinence -rectal fistula -osteomyelitis pubis	<ul style="list-style-type: none"> • Non-clinical performance testing • Software verification, validation, and hazard analysis • <i>In vivo</i> testing • Clinical testing • Labeling • 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	<ul style="list-style-type: none"> • Clinical testing • Labeling • Physician training
Mechanical injury from unintentional movement of ultrasound components: -patient rectal injury -operator hand injury	<ul style="list-style-type: none"> • Software verification, validation, and hazard analysis • Clinical testing • Labeling • Physician training
Infection	<ul style="list-style-type: none"> • Sterilization validation

	<ul style="list-style-type: none"> • Reprocessing validation • Shelf life validation • Labeling
Electrical shock/Electromagnetic interference	<ul style="list-style-type: none"> • Electrical safety testing • Electromagnetic compatibility testing • Labeling
Adverse tissue reaction	<ul style="list-style-type: none"> • Biocompatibility testing

In combination with the general controls of the FD&C Act, the high intensity ultrasound system for prostate tissue ablation is subject to the following special controls:

- (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:
 - (A) Characterization of acoustic pressure and power output at clinically relevant levels;
 - (B) Measurement of targeting accuracy and reproducibility of high intensity ultrasound output;
 - (C) Ultrasound-induced heating verification testing at target and non-target tissues;
 - (D) Electrical safety testing; and
 - (E) 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:
 - (A) Use all safety features of the device;
 - (B) Accurately target the high intensity ultrasound energy within the desired region of the prostate; and
 - (C) Perform the ablation procedure in a manner that minimizes damage to non-target tissues.
- (10) Labeling must include:
 - (A) A section that summarizes the clinical testing results, including the adverse event profile and evidence of prostate ablation achieved.
 - (B) An expiration date or shelf life for single use components.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 high intensity ultrasound system for prostate tissue ablation they intend to market prior to marketing the device and receive clearance to market from FDA.

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); 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 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.

If you have any questions concerning this classification order, please contact Mr. John Baxley at (301) 796-6549.

Sincerely,

 Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
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