November 4, 2026

Theraclion SA
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market St.
Floor 23
Philadelphia, Pennsylvania 19103

Re: DEN250063
Trade/Device Name: Sonovein System
Regulation Number: 21 CFR 878.4415
Regulation Name: High intensity therapeutic ultrasound system for thermal vein coagulation
Regulatory Class: Class II
Product Code: SJR
Dated: December 8, 2025
Received: December 8, 2025

Dear Janice Hogan:

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 Sonovein System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Sonovein is an ultrasound therapeutic medical device which is intended for the coagulation of blood vessels in patients with superficial vein reflux in the Greater Saphenous Vein (GSV) segments.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Sonovein System, and substantially equivalent devices of this generic type, into Class II under the generic name high intensity therapeutic ultrasound system for thermal vein coagulation.

FDA identifies this generic type of device as:

> **High intensity therapeutic ultrasound system for thermal vein coagulation.** A high intensity therapeutic ultrasound system for thermal vein coagulation is a prescription, non-invasive device using therapeutic ultrasound to produce localized, mechanical motion for the purpose of delivering localized heating for vein coagulation.

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 December 8, 2025, FDA received your De Novo requesting classification of the Sonovein System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Sonovein System 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, the Sonovein System 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:

Risks to Health	**Mitigation Measures**
Thermal injury from high intensity ultrasound exposure	Non-clinical performance testing Software verification, validation and hazard analysis Animal performance testing Human factors testing Clinical performance testing Labeling
Mechanical injury from high intensity ultrasound exposure (pain, hematoma)	Software verification, validation and hazard analysis Clinical performance testing Labeling
Unsuccessful vein closure and reflux from inadequate thermal coagulation	Clinical performance testing
Adverse tissue reaction	Biocompatibility evaluation
Electrical shock / Electromagnetic interference	Electrical safety testing Electromagnetic compatibility testing Labeling

In combination with the general controls of the FD&C Act, the high intensity therapeutic ultrasound system for thermal vein coagulation is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated

conditions of use. Testing must document the rate of vein closure and adverse event profile.

(2) Animal performance testing must demonstrate that the device thermally coagulates the blood vessels and must characterize the chronic safety profile of the device, including injury to adjacent, non-target tissue.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
- (i) Characterization of acoustic power output at clinically relevant levels and acoustic field;
- (ii) Measurement of targeting accuracy of high intensity ultrasound output;
- (iii) Ultrasound-induced heating;
- (iv) Imaging transducer quality;
- (v) Device motion accuracy and resolution; and
- (vi) Device range of motion.

(4) Performance data must support the electrical safety and electromagnetic compatibility of the device.

(5) All patient-contacting components of the device must be demonstrated to be biocompatible.

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

(7) Human factors/usability testing must demonstrate that the device can be safely and effectively used by intended users.

(8) Labeling must include the following:
- (i) A section that summarizes the clinical testing results, including the adverse event profile and evidence of vein ablation achieved;
- (ii) Information related to the limitations of device performance or subpopulations for which the device may not perform as expected;
- (iii) Information needed to implement the workflow (planning, positioning, calibration, energy setting, treatment, monitoring);
- (iv) Warnings to avoid unsafe exposure to any energy-emitting components of the device;
- (v) An expiration date or shelf life for single use components; and
- (vi) Reprocessing steps and use life for multi-patient use components.

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download)

and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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 therapeutic ultrasound system for thermal vein coagulation 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (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).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (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 Mykhaylo Nosovskyy at 301-796-3745.

Sincerely,

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Julie Morabito, Ph.D.
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DHT4A: Division of General Surgery Devices
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