

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. 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 final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for hyperoxia monitoring devices adjunct to pulse oximetry. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

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 normally 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification 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; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; 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 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

- 1. The authority citation for part 870 continues to read as follows:

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

- 2. Add § 870.2720 to subpart C to read as follows:

§ 870.2720 Hyperoxia monitoring device adjunct to pulse oximetry.

(a) *Identification.* A hyperoxia monitoring device adjunct to pulse oximetry is a device that monitors elevated hemoglobin oxygen saturation levels as an adjunct to arterial oxygen saturation monitoring.

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

(1) Clinical performance testing under anticipated conditions of use must evaluate the accuracy of hyperoxia monitoring by the device and evaluate all adverse events.

(2) Human factors/usability testing must demonstrate that the user can correctly use the device, based solely on reading the instructions for use.

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

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

(5) Performance testing must validate the reprocessing instructions for the device, including demonstration of device performance after repeated cleaning and disinfection.

(6) Software verification, validation, and hazard analysis must be performed. Performance testing must demonstrate compatibility with pulse oximeter devices labeled to be compatible with the device.

(7) Labeling must include:

(i) Cleaning and disinfection instructions;

(ii) A summary of the clinical performance testing with the device;

(iii) A warning against over-reliance on device output without using arterial blood gas values for confirmation; and

(iv) Instructions to monitor oxygen delivery and patient clinical/

cardiovascular status when device output changes.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2026–N–10992]

Medical Devices; General and Plastic Surgery Devices; Classification of the Focused Ultrasound System for Non-Thermal, Mechanical Tissue Ablation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the focused ultrasound system for non-thermal, mechanical 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 classification of the focused ultrasound system for non-thermal, mechanical tissue ablation. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 6, 2026. The classification was applicable on October 6, 2023.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD 20993–0002, 301–796–6412, Cal.Rabang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the focused ultrasound system for non-thermal, mechanical tissue ablation into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device 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 (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and

Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (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 is required to 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 placed 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 section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less

burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 2, 2022, FDA received HistoSonics, Inc.’s request for De Novo classification of the Edison 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 the safety and effectiveness of the device, 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 section 513(a)(1)(B) of the FD&C Act). 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 October 6, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.4405.¹ We have named the generic type of device “focused ultrasound system for non-thermal, mechanical tissue ablation,” and it is identified as a device that uses focused ultrasound to mechanically ablate soft tissue. The device is not intended to thermally ablate tissue.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR FOCUSED ULTRASOUND SYSTEM FOR NON-THERMAL, MECHANICAL TISSUE ABLATION

Identified risks to health	Mitigation measures
Impaired tissue or organ function, abscess, pain, or other adverse events downstream of tissue ablation.	Clinical performance testing; Labeling; and Human factors testing.
Acoustic path, non-targeted tissue injury	Clinical performance testing; Human factors testing; Animal performance testing; and Non-clinical performance testing.
Tissue injury due to device malfunction or misuse	Clinical performance testing; Software verification, validation, and hazard analysis; Non-clinical performance testing; Labeling; and Human factors testing.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock or electromagnetic interference	Electrical safety testing; Electromagnetic compatibility testing; and Labeling.

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to

indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. 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 final order. FDA supports the principles of the “3Rs,” to replace, reduce, and/or refine animal use in testing when feasible. 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 whether such an alternative method could be assessed for equivalency to an animal test method.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for focused ultrasound systems for non-thermal, mechanical tissue ablation. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

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 normally 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification 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; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; 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 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4405 to subpart E to read as follows:

§ 878.4405 Focused ultrasound system for non-thermal, mechanical tissue ablation.

(a) *Identification.* This device uses focused ultrasound to mechanically ablate soft tissue. The device is not intended to thermally ablate tissue.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must document the adverse event profile and characterize tissue destruction.

(2) Animal performance testing must demonstrate that the device mechanically destroys targeted tissue while characterizing the chronic safety profile, including thermal and mechanical 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) Acoustic characterization at clinically relevant settings;

(ii) Determination of the minimum drive voltages necessary to sustain a bubble cloud in the target tissue;

(iii) Validation of mechanisms to prevent energy delivery that would result in adverse thermal effects;

(iv) Availability of real-time monitoring during the procedure;

(v) Validation that the treatment zone is limited to the defined target tissue; and

(vi) Validation of mechanisms to prevent, pause, and terminate ablation in the event of device failure.

(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 testing must demonstrate that the user can safely and correctly use the device.

(8) Labeling must include the following:

(i) A warning that focused ultrasound ablation should only be considered in patients with sufficient functional reserve to withstand the destruction of the planned volume of tissue;

(ii) A statement that the device has not been evaluated for the treatment of any specific disease or condition; and

(iii) A detailed summary of the clinical testing with the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF THE TREASURY

Office of the Secretary

31 CFR Part 1

Privacy Act Exemptions

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of the Treasury (Treasury) is issuing a final rule, exempting a new system of records entitled “Department of the Treasury, Treasury .032—Federal Program Waste, Fraud, and Abuse Tip Intake and Referral Records” from certain provisions of the Privacy Act. This system of records is established to support the receipt, maintenance, review, triage, and referral of tips, complaints, allegations, leads, supporting information, and related correspondence concerning suspected waste, fraud, abuse, improper payments, misuse of Federal funds, or other misconduct affecting Federal programs. The exemption is intended to protect investigatory material compiled for law enforcement purposes.

DATES: This rule is effective on November 5, 2026.