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J. Randolph Babbitt,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2011–N–0499]

Medical Devices; General and Plastic Surgery Devices; Classification of the Focused Ultrasound Stimulator System for Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the focused ultrasound stimulator system for aesthetic use into class II (special controls). The special control(s) that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use.'' The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective August 19, 2011. The classification was effective on September 11, 2009.

FOR FURTHER INFORMATION CONTACT: Richard Felten, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1436, Silver Spring, MD 20993–0002, 301–796–6392.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will 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 this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 14, 2008 classifying the Ulthera™ Focused Ultrasound Stimulator System for Aesthetic Use into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On April 11, 2008, Ulthera, Inc. submitted a petition requesting classification of the Ulthera™ Focused Ultrasound Stimulator System for Aesthetic Use under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name Focused Ultrasound Stimulator System for Aesthetic Use and it is identified as a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for noninvasive aesthetic use.

FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

- Thermal injury from focused ultrasound exposure (thermal damage), such as erythema, edema, pigmentary changes, and pain. These are commonly seen risks associated with any energy delivery system that creates tissue heating. This risk is addressed by recommended treatment parameters that have been shown to be safe with little or no adverse effects. In addition, the recommended labeling includes warnings related to patient reaction in terms of pain and information to user in terms of observable skin reactions that are known to be precursors to the potential thermal adverse effects.
- Mechanical injury from focused ultrasound exposure (mechanical damage) induced by either cavitation or noncavitation means. Notable effects are pain and petechial hemorrhage (red spots). Further, skin contour changes due to scar formation are possible. This risk is addressed by recommended treatment parameters that have been shown to be safe with little or no adverse effects.
- Ocular injury represents a potentially unique serious risk from inadvertent ultrasound exposure. The mitigation of this risk is addressed by labeling recommendations to warn the user not to expose the eye to ultrasound radiation, as well as specific directions intended to ensure complete handpiece skin contact, which further reduces the risk of scattered ultrasound energy reaching the eye.
- Electrical shock is addressed by recommended testing of the device according to recognized U.S. and International Standards specifically designed to determine and measure potential electrical safety. Again, the recommended device labeling also includes specific warnings for the user in terms of device placement, appropriate electrical wiring needs, reminders to periodically check device wiring and accessories for damage, and avoidance of use of the device in

environments where electrical shock is possible.

• Inflammation/foreign body response relates to possible issues that can occur following any type of therapeutic process in which tissue injury could occur. This risk is typical for any surgical procedure and is addressed by the recommendations to follow routine standard of care for any surgical patient that could include posttreatment skin care including use of moisturizers, antibacterial creams, and avoidance of potential risks such as use of perfumes, facial creams, and sunlight.

• Use error represents those risks to the patient that can occur from improper use of the device. In order to address this potential risk, we recommend the manufacturer provide a detailed operator manual which contains information on possible risks and hazards and how these should be avoided and clear recommended safe treatment procedures that include information on device settings for treatment, clear information on how the device is to be used during treatment, and recommended posttreatment care.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Recommended mitigation measures
Thermal Injury from Focused Ultrasound Exposure (Thermal Damage)	Section 6. Bench Testing. Section 7: Software Validation. Section 8. Animal Testing. Section 9. Clinical Testing. Section 13. Labeling.
Mechanical Injury from Focused Ultrasound Exposure (Cavitation or other Mechanical Damage).	Section 6. Bench Testing. Section 7. Software Validation. Section 8. Animal Testing. Section 9. Clinical Testing. Section 13. Labeling.
Ocular Injury	Section 13. Labeling.
Electrical Shock	Section 12. Electrical and Mechanical Safety Performance Testing.
Inflammation/Foreign Body Response	Section 10. Biocompatibility.
Use Error (Eye Injury)	Section 13. Labeling.

FDA believes that the special controls guidance document, ''Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use,'' in addition to general controls, addresses the risks to health and provides reasonable assurance of the safety and effectiveness of the device. Therefore, on September 11, 2009, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 878.4590.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for focused ultrasound stimulator system for aesthetic use will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

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. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the focused ultrasound stimulator system for aesthetic use they intend to market.

Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use'' that will serve as the special control for this device.

II. 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross

Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain state requirements ''different from or in addition to'' certain federal requirements applicable to devices. 21 U.S.C. 360k; See *Medtronic Inc.,* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). The special controls established by this final rule create ''requirements'' for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–742 (9th Cir. 1991).

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This final rule establishes as special controls a guidance document that refers to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by OMB under the PRA.

VI. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Ulthera, Inc., April 11, 2008.

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 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4590 is added to subpart E to read as follows:

§ 878.4590 Focused ultrasound stimulator system for aesthetic use.

(a) *Identification.* A Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for noninvasive aesthetic use.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use.'' See § 878.1(e) for the availability of this guidance document.

Dated: July 15, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 41

[TD 9537]

RIN 1545–BK36

Highway Use Tax; Filing and Payment for Taxable Period Beginning July 1, 2011

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations that provide guidance on the filing of Form 2290 (''Heavy Highway Vehicle Use Tax Return'') and payment of the associated highway use tax for the taxable period beginning July 1, 2011. The regulations affect owners and operators of highway motor vehicles with a taxable gross weight of 55,000 pounds or more. The text of the temporary regulations also serves as the text of the proposed regulations on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on July 20, 2011.

Applicability Date: For dates of applicability, see §§ 41.6001–2T(d), 41.6071(a)–1T(c)(3), and 41.6151(a)–1T(b).

FOR FURTHER INFORMATION CONTACT: Natalie Payne, (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Highway Use Tax Regulations (26 CFR Part 41) under section 4481 of the Internal Revenue Code (Code).

Section 4481 imposes a tax on the use in any taxable period of a highway motor vehicle with a taxable gross weight of 55,000 pounds or more. The person in whose name the vehicle is registered at the time of the first use must pay the tax. The rate of tax is based on the weight of the vehicle with a maximum of $550 per vehicle per taxable period (the standard amount).

Generally, a ''taxable period'' is the year that begins on July 1 and ends on the following June 30. For the taxable period beginning on July 1, 2011, however, section 4482(c)(4) of present law provides that the taxable period ends at the close of September 30, 2011. For this three month period, the tax rate is a reduced amount that is 25 percent of the tax rate for a 12-month period.

Section 41.6011(a)–1(a)(1) requires each person that is liable for the tax imposed by section 4481 to file a return for each taxable period and § 41.6011(a)–1(b) provides that the return is Form 2290, ''Heavy Highway Vehicle Use Tax Return.''

The due date for filing Form 2290 is not prescribed by statute and section 6071 provides that when the Code does not set the time for filing a return, the Secretary is to prescribe such time by regulations. Under § 41.6071(a)–1(a), Form 2290 generally must be filed by the last day of the month following the month in which a person becomes liable for tax. For most taxpayers, their first use of a vehicle in a taxable period occurs in July and thus their return is due by August 31.

Section 41.6001–2(b) provides, generally, that a State that receives an application to register a highway motor vehicle must receive from the applicant ''proof of payment'' of the tax imposed by section 4481(a). Section 41.6001–2(c) specifies that this proof of payment generally consists of a receipted