(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com*.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on January 25, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–2433 Filed 2–4–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2010–D–0645]

Medical Devices; General and Plastic Surgery Devices; Classification of Contact Cooling System for Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the contact cooling system for aesthetic use into class II (special controls). The special control that will apply to the device is the guidance document entitled "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use." The Agency is classifying the device into class II (special controls) in order to provide reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device type.

DATES: *Effective Date:* March 9, 2011.

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, 301–796–6392.

SUPPLEMENTARY INFORMATION:

I. What is the background of this rulemaking?

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and the Food and Drug Administration Modernization Act (Pub. L. 107–250) established a comprehensive system for regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

FDA refers to devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as postamendments devices. Postamendments devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or class II in accordance with section 513(f)(2) of the FD&C Act; or FDA issues an order finding the device to be substantially equivalent, under section 513(i) 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 FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

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 that has not previously been classified into class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA will, within 60 days of receiving this request, classify the device by written order. 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 this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 7, 2009, classifying the Zeltiq Lipolysis 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 October 13, 2009, Zeltiq™ Aesthetic, Inc., submitted a petition requesting classification of the lipolysis 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). FDA classifies devices into class II if general controls by themselves are insufficient 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 contact cooling system for aesthetic use can be classified into class II with the establishment of special controls. FDA believes these special controls will provide assurance of the safety and effectiveness of the device.

The device was assigned the generic name "Cooling System for Aesthetic Use" and it is identified as a cooling system for 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.

- Discomfort and pain during and following treatment are possible due to the application of mechanical or vacuum massage at levels in excess of those recommended in the labeling. These effects and tenderness at the treatment site may also occur following treatment. Prevention of these effects are addressed by adequate bench testing demonstrating that the feedback controls for temperature/cooling are functional and do maintain target temperature within the stated value. Proper function of mechanical controls to insure use of the mechanical or vacuum massager within safe limits

should be confirmed as part of bench testing.

• 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.

• 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 post treatment care.

• Tissue damage from uncontrolled cooling is a risk which is addressed by the above stated bench testing of the temperature control system. In addition the labeling provided shall give recommended safe use parameters in terms of temperature setting and duration of treatment with these parameters supported by animal or clinical data.

• Systemic response to cold is a potential hazard for individuals who may have underlying cold sensitive health conditions or reduced skin sensitivity due to other medical conditions. This risk is addressed through the device labeling which provides appropriate cautions, warnings and contradictions for such cold sensitive conditions.

• Skin inflammation or foreign body responses can be an issue for individuals based on the skin contact nature of this device. This type of skin irritation is prevented by appropriate testing for biocompatibility of the contact materials when in contact with skin.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Recommended mitigation measures
Discomfort, Pain, Tenderness	Section 6. Bench Testing Section 9. Clinical Testing Section 13. Labeling
Thermal Injury (Tissue Damage from Uncontrolled Cooling)	Section 6. Bench Testing Section 7. Software Validation Section 8. Animal Testing Section 9. Clinical Testing Section 11. Electromagnetic Compatibility (IEC 60601–1–2) Section 13. Labeling
Systemic Response to Cold	Section 9. Clinical Testing Section 13. Labeling
Electrical Shock	Section 12. Electrical and Mechanical Safety (IEC 60601–1)
Inflammation/Foreign Body Response	Section 10. Biocompatibility (ISO 10993)
Use Error	Section 13. Labeling

FDA believes that the special controls, in addition to general controls, address the risks to health identified in table 1 of this document and provide reasonable assurance of the safety and effectiveness of the device type. Therefore, on August 24, 2010, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this device classification by adding 21 CFR 878.4340.

Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for cooling system for aesthetic use device intended for the disruption of adipocyte cells intended for non-invasive 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 requirement under section 510(k), 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 and, therefore, the type of device 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 cooling system for aesthetic use that they intend to market.

II. What is the environmental impact of this rule?

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. What is the analysis of impacts of this rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs 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 the Executive order.

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 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 $135 million, using the most current (2009) 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. Does this final rule have federalism implications?

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* v. *Lohr* 518 U.S. 470 (1996); *Riegel* v. *Medtronic,* 552 U.S. 312 (2008). The special controls established by this final rule create "requirements" to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors have flexibility in how they meet those requirements. Cf. *Papike* v. *Tambrands,* Inc., 107 F. 3d 737, 740–42 (9th Cir. 1997).

V. How does this rule comply with the paperwork reduction act of 1995?

This final rule contains no collections of new information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing availability of the guidance for the final rule. This guidance entitled "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use" references previously approved collections of information found in FDA regulations.

VI. What references are on display?

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 Zeltiq Aesthetics, October 13, 2009.

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 878.4340 is added to subpart E to read as follows:

§ 878.4340 Contact cooling system for aesthetic use.

(a) *Identification.* A contact cooling system for aesthetic use is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells intended for non-invasive aesthetic use.

(b) *Classification.* Class II (special controls). The special controls for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use." See § 878.1(e) for the availability of this guidance document.

Dated: February 1, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–2552 Filed 2–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9514]

RIN 1545–BG34

Time and Manner for Electing Capital Asset Treatment for Certain Self-Created Musical Works

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation and removal of temporary regulation.

SUMMARY: This document contains a final regulation that provides the time and manner rules for electing to treat the sale or exchange of a musical composition or a copyright in a musical work created by the taxpayer (or received by the taxpayer from the composition or work's creator in a transferred basis transaction) as the sale or exchange of a capital asset. The regulation reflects changes to the law made by the Tax Increase Prevention and Reconciliation Act of 2005 and the Tax Relief and Health Care Act of 2006. The regulation affects taxpayers who elect to treat gain or loss from such a sale or exchange as capital gain or loss.

DATES: *Effective Date:* This regulation is effective on February 7, 2011.

Applicability Date: For date of applicability, see § 1.1221–3(d).

FOR FURTHER INFORMATION CONTACT: Jamie Kim, (202) 622–4950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains an amendment to the Income Tax Regulations (26 CFR part 1). On February 8, 2008, a temporary regulation (TD 9379) was published in the **Federal Register** (73 FR 7464) that provided the time and manner rules for electing capital asset treatment for certain self-created musical works. A notice of proposed rulemaking (REG–153589–06) cross-referencing the temporary regulation also was published in the **Federal Register** (73 FR 7503) on February 8, 2008. No comments in response to the notice of proposed rulemaking or requests to hold a public hearing were received, and no hearing was held. This Treasury decision adopts the proposed regulation with minor changes and removes the temporary regulation.

Section 1221(a) of the Internal Revenue Code (Code) generally provides that capital assets include all property