interconnection-related system impact studies.

10. Similarly, we deny TAPS's request that the information from system impact studies be made available on a non-discriminatory basis to all interested transmission customers. TAPS erroneously assumes that the Commission determined that system impact studies (or other studies) performed in response to interconnection requests are planning activities that may be conducted by marketing function employees. Marketing function employees may not perform system impact studies (or other studies) in response to interconnection requests since the studies would involve the use and analysis of non-public transmission information. As we stated in Order No. 717, planning personnel who do not qualify as marketing function employees may discuss information with transmission function employees.[12] However, we reiterated that the No Conduit Rule applied in this situation, stating that if transmission employees share transmission function information with planning personnel, the planning personnel may not pass such information on to marketing function employees. The clear implication of these statements is that while planning studies may be conducted by personnel who are not transmission function employees, marketing function employees may not participate in the preparation of studies which involve the use and analysis of non-public transmission information.[13]

11. We grant TAPS's clarification request that when an employee performs a system impact study in response to a transmission service request, that employee is a transmission function employee regardless of the duration of the requested transmission service. This clarification is consistent with our previous conclusion that the designation of an employee as a transmission function employee does not depend upon the duration of the requested transmission service.[14]

III. Document Availability

12. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

13. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

14. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

IV. Effective Date

15. Changes to Order No. 717–C adopted in this order on rehearing and clarification are effective May 16, 2011.

By the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–9059 Filed 4–13–11; 8:45 am]

BILLING CODE 6717–01–P

[12] Order No. 717, FERC Stats. & Regs ¶ 31,280 at P 151.

[13] Order No. 717 specifically recognized that there are employees who are neither transmission function employees nor marketing function employees. *See, e.g.,* Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 174 ("Transmission function employees are no longer barred from interacting with all the employees of a marketing or energy affiliate (only marketing function employees)").

[14] *See Standards of Conduct for Transmission Providers,* Order No. 717–A, 74 FR 54463 (Oct. 22, 2009), FERC Stats. & Regs. ¶ 31,297, at P 27 (2009).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2011–N–0188]

Medical Devices; General and Plastic Surgery Devices; Classification of the Low Level Laser System for Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the low level laser system for aesthetic use into class II (special controls). The special control(s) that will apply to the device is entitled "Class II Special Controls Guidance Document: Low Level Laser 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. 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: This rule is effective May 16, 2011. The classification was effective on August 24, 2010.

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. What is the background of this rulemaking?

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 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 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

December 22, 2008, classifying the Erchonia Low Level Laser 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 January 5, 2009, Erchonia, Inc., submitted a petition requesting classification of the Erchonia Low Level Laser 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 Low Level Laser System for Aesthetic Use, and it is identified as a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells 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.

- Ocular injury is a recognized hazard from laser optical systems because of the unique physical characteristics of laser light; that is, this optical radiation is easily transmitted into the eye as a very bright, intense light beam that may produce lesions on the retina. This hazard is addressed by device labeling, which includes recommendations for not looking directly at the laser beam and the wearing of appropriate laser safety eyewear by both the user and patient. The labeling also includes information defining the size of the area within which this optical hazard exists.
- 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.
- Unintended cell damage is a potential risk from use of low level lasers if improper or incorrect energy is used to initiate the process of causing lipid and fat leakage from the target adipocyte cells. The intended effect on the adipocyte cells is the creation of pores that results in the lipid or fat leaving these specialized cells; however, if the laser parameters are not correct, no effect may occur in terms of adipocyte change or other non-adipocyte cells may be affected, resulting in alteration of other cellular membranes or transport systems that could result in unintended cell death.
- 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.

FDA believes that the class II special controls guidance document will aid in mitigating the potential risks to health as described in table 1 of this document.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Recommended mitigation measures
Ocular Injury	Section 6. Bench Testing. Section 7. Software Validation. Section 8. Clinical Testing. Section 12. Labeling.
Electrical Shock	Section 11. Electrical and Mechanical Safety Performance Testing (IEC 60601–1). Section 12. Labeling.
Unintended Cell Damage	Section 6. Bench Testing. Section 7. Software Validation. Section 8. Clinical Testing. Section 9. Biocompatibility. Section 10. Electromagnetic Compatibility (IEC 60601–1–2). Section 12. Labeling.
Use Error	Section 12. Labeling.

FDA believes that the special controls guidance, "Low Level Laser System for Aesthetic Use," in addition to general controls, address the risks to health and provide reasonable assurance of the safety and effectiveness of the device. Therefore, on August 24, 2010, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 878.5400.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for low level laser 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 low level laser system for aesthetic use 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 and 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 and so it is not subject to review under 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 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 $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 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. (See section 521 of the FD&C Act (21 U.S.C. 360k); See *Medtronic, Inc.,* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic, Inc.,* 128 S. Ct. 999 (2008)). The special controls established by this final rule creates "requirements" for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. (See *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?

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. 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: Low Level Laser System for Aesthetic Use" that will serve as the special control for this device. This notice contains an analysis of the paperwork burden for the guidance document.

VI. References

The following references have 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 Erchonia, Inc., January 5, 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 878.5400 is added to subpart F to read as follows:

§ 878.5400 Low Level Laser System for Aesthetic Use

(a) *Identification.* A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive aesthetic use.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use." See § 878.1(e) for the availability of this guidance document.

Dated: April 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8944 Filed 4–13–11; 8:45 am]

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