(d) Civil money penalties that are assessed under this subpart are subject to annual adjustments to account for inflation as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74, sec. 701, 129 Stat. 584) (*see also* 12 CFR 308.132(d)(17)).

* * * * *

PART 327—ASSESSMENTS

■ 4. The authority citation for part 327 continues to read as follows:

Authority: 12 U.S.C. 1441, 1813, 1815, 1817–19, 1821.

■ 5. Revise § 327.3(c) to read as follows:

§ 327.3 Payment of assessments.

* * * * *

(c) *Necessary action, sufficient funding by institution.* Each insured depository institution shall take all actions necessary to allow the Corporation to debit assessments from the insured depository institution's designated deposit account. Each insured depository institution shall, prior to each payment date indicated in paragraph (b)(2) of this section, ensure that funds in an amount at least equal to the amount on the quarterly certified statement invoice are available in the designated account for direct debit by the Corporation. Failure to take any such action or to provide such funding of the account shall be deemed to constitute nonpayment of the assessment. Penalties for failure to timely pay assessments are provided for at 12 CFR 308.132(d)(9).

* * * * *

Dated at Washington, DC, this 21st day of June, 2016.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–15027 Filed 6–28–16; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–N–1618]

Medical Devices; General and Plastic Surgery Devices; Classification of the Electrosurgical Device for Over-the-Counter Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the electrosurgical device for over-the-counter aesthetic use into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the electrosurgical device for over-the-counter aesthetic use's classification. 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 order is effective June 29, 2016. The classification was applicable on December 18, 2015.

FOR FURTHER INFORMATION CONTACT: Long Chen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G472, Silver Spring, MD 20993–0002, 301–796–6389, *Long.Chen@fda.hhs.gov.*

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 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On January 13, 2015, EndyMed Medical Ltd., submitted a request for classification of the Newa™ device 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 request 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 request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 18, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4420.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an electrosurgical device for over-the-counter aesthetic use will need to comply with the special controls named in this final order.

The device is assigned the generic name electrosurgical device for over-the-counter aesthetic use, and it is identified as a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.

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

TABLE 1—ELECTROSURGICAL DEVICE FOR OVER-THE-COUNTER AESTHETIC USE RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Infection	Cleaning Validation. Labeling.
Adverse Tissue Reaction	Biocompatibility.
Skin Overheating/Burn	Clinical Performance Testing. Non-clinical Performance Testing. Software Verification, Validation and Hazards Analysis. Labeling.
Electromagnetic Interference/Electrical Shock	Electromagnetic Compatibility Testing. Electrical Safety Testing. Labeling.
Worsening Aesthetic Outcomes	Clinical Performance Testing.
Use Error	Usability Study. Labeling.
Failure to Identify Correct Population and Condition	Label Comprehension and Self-Selection Study. Labeling.

FDA believes that the special controls, in addition to the general controls, address these risks to health and provide reasonable 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 electrosurgical device for over-the-counter aesthetic use they intend to market.

II. Analysis of 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. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. 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. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.*

1. DEN150005: De Novo Request per 513(f)(2) from EndyMed Medical Ltd., dated January 13, 2015.

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 § 878.4420 to subpart E to read as follows:

§ 878.4420 Electrosurgical device for over-the-counter aesthetic use.

(a) *Identification.* An electrosurgical device for over-the-counter aesthetic use is a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.

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

(1) Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested: Over-heating, power accuracy radiofrequency, pulse cycle, waveform, pulse duration, and device characterization parameters.

(2) Label comprehension and self-selection performance evaluation must demonstrate that the intended over-the-counter users can understand the package labeling and correctly choose the device for the indicated aesthetic use.

(3) Usability performance evaluation must demonstrate that the over-the-counter user can correctly use the device, based solely on reading the

directions for use, to treat the indicated aesthetic use.

(4) Clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use to achieve the intended aesthetic results.

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

(6) Instructions for cleaning the device must be validated.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety, including the mechanical integrity, of the device.

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

(9) Labeling must include:

(i) Warnings, precautions, and contraindications to ensure the safe use of the device for the over-the-counter users.

(ii) A statement that the safety and effectiveness of the device's use for uses other than the indicated aesthetic use are not known.

(iii) A summary of the clinical information used to establish effectiveness for each indicated aesthetic usage and observed adverse events.

Dated: June 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15381 Filed 6–28–16; 8:45 am]

BILLING CODE 4164–01–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 205

RIN 0412–AA69

Participation by Religious Organizations in USAID Programs

AGENCY: U.S. Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This rule amends AID regulations to address provisions which are more restrictive than relevant Federal case law and relevant legal opinions issued by the United States Department of Justice with respect to the applicability of the Establishment Clause to the use of Federal funds.

DATES: This rule will be effective July 29, 2016.

FOR FURTHER INFORMATION CONTACT: Mark Brinkmoeller, Director, Center for Faith-Based and Community Initiatives, USAID, Room 6.07–023, 1300 Pennsylvania Avenue NW., Washington, DC 20523; *telephone:* (202) 712–4080 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On October 20, 2004, USAID published its final rule (the ''Current Rule'') on participation by religious organizations in USAID programs (69 FR 61716, codified at 22 CFR parts 202, 205, 211, and 226). The Current Rule implemented Executive Branch policy that, within the framework of Constitutional guidelines, religious organizations should be able to compete on an equal footing with other organizations for USAID funding. The Current Rule revised USAID regulations pertaining to grants, cooperative agreements and contracts awarded for the purpose of administering grant programs to ensure their compliance with this policy and to clarify that religious organizations are eligible to participate in programs on the same basis as any other organization, with respect to programs for which such other organizations are eligible.

Among other things, the Current Rule provided that USAID funds could be used for the acquisition, construction, or rehabilitation of structures only to the extent that those structures were used for conducting eligible activities under the specific USAID program. Where a structure also is used for inherently religious activities, the Current Rule clarified that USAID funds could not exceed the cost of those portions of the acquisition, construction, or rehabilitation that were attributable to eligible activities. The Current Rule went on to state that USAID funds could not be used for acquisition, construction, or rehabilitation of sanctuaries, chapels, or any other room that a religious congregation that is a recipient or sub-recipient of USAID assistance uses as its principal place of worship. Since the implementation of the Current Rule, USAID has found that this provision has constricted its ability to pursue the national security and foreign policy interests of the United States overseas.

The Supreme Court has not addressed whether the Establishment Clause applies extraterritorially. In *Lamont* v. *Woods,* 948 F.2d 825, 834 (2d Cir. 1991), the Second Circuit concluded that the Establishment Clause applies to government grants to foreign religious institutions located abroad. In dicta in *Lamont,* the court said that ''domestic Establishment Clause jurisprudence has more than enough flexibility to accommodate any special circumstances created by the foreign situs of the expenditures, although the international dimension does . . . enter into the analysis.'' [1] The Second Circuit also suggested that the requirements of the Establishment Clause might be relaxed in certain circumstances, noting that ''the fact that a particular grantee is the only channel for aid, or that a given country has no secular education system at all, may warrant overriding the usual Establishment Clause presumption.'' *Id.,* at 842. Under these circumstances, the Second Circuit said, ''[t]he court would then scrutinize the manner in which the institution may use its grant in an attempt to ascertain whether, in reality, the grant would have the principal or primary effect of advancing religion.'' *Id.* The Second Circuit also indicated that the foreign policy ramifications of the case made it particularly inappropriate to adopt a mechanical approach to the Establishment Clause. The final rule will permit USAID to take these considerations into account, in consultation with DOJ.

In addition, the Current Rule is more restrictive than at least two legal opinions written by the U.S. Department of Justice's Office of Legal Counsel. In a September 25, 2002 Memorandum Opinion for the General Counsel of FEMA, *Authority of FEMA to provide Disaster Assistance to Seattle Hebrew Academy,* the Office of Legal Counsel concluded that FEMA could provide a disaster assistance grant to the Seattle Hebrew Academy, for repairs to the Academy following the Nisqually Earthquake on February 28, 2001. The Current Rule may not permit USAID to provide assistance under similar circumstances to a religious school or other religious structure in the aftermath of a natural disaster overseas. In an April 30, 2003 Memorandum Opinion for the Solicitor of the Department of the Interior, *Authority of the Department of the Interior to Provide Historic Preservation Grants to Historic Religious Properties Such as the Old North Church,* the Office of Legal Counsel concluded that the Establishment Clause did not bar the award of historic preservation grants to the Old North Church or other active houses of worship that qualify for such assistance. The current rule does not permit the use of USAID funds for acquisition, construction, or rehabilitation of structures to the extent that those structures are used for inherently religious activities, and further does not permit the acquisition, construction, or rehabilitation of sanctuaries, chapels, or any other room that a religious congregation uses as its principal place of worship, and thus likely would not

[1] *Id.* at 841.