September 15, 2016, is amended as follows:

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.

* * * * *

AEA NY E4 Ithaca, NY [Amended]

Ithaca Tompkins Regional Airport, Ithaca, NY
(Lat. 42°29′29″ N., long. 76°27′31″ W.)
Ithaca VOR/DME
(Lat. 42°29′42″ N., long. 76°27′35″ W.)

That airspace extending upward from the surface from the 4-mile radius of the Ithaca Tompkins Regional Airport to the 5.7-mile radius of the airport; clockwise from the 329° bearing to the 081° bearing from the airport; that airspace from the 4-mile radius of Ithaca Tompkins Regional Airport to the 8.7-mile radius of the airport extending clockwise from the 081° bearing to the 137° from the airport; that airspace from the 4-mile radius of Ithaca Tompkins Regional Airport; to the 6.6-mile radius of the airport, extending clockwise from the 137° bearing to the 170° bearing from the airport; that airspace from the 4-mile radius to the 5.7-mile radius of the Ithaca Tompkins Regional Airport, extending clockwise from the 170° bearing to the 196° bearing from the airport; and that airspace within 2.7 miles each side of the Ithaca VOR/DME 305° radial extending from the 4-mile radius of Ithaca Tompkins Regional Airport to 7.4 miles northwest of the Ithaca VOR/DME. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Airport/Facility Directory.

Issued in College Park, Georgia, on September 7, 2016.

Joey L. Medders,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2016–22741 Filed 9–21–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2016–N–2656]

Medical Devices; Ophthalmic Devices; Classification of Strabismus Detection Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the strabismus detection device 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 strabismus detection device'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 September 22, 2016. The classification was applicable on June 8, 2016.

FOR FURTHER INFORMATION CONTACT: Elvin Ng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2431, Silver Spring, MD 20993–0002, 240–402–4662, *elvin.ng@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). 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 shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On December 11, 2013, RebiScan, Inc., submitted a request for classification of the Pediatric Vision Scanner under section 513(f)(2) of the FD&C Act.

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). 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 June 8, 2016, 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 886.1342.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a strabismus detection device will need to comply with the special controls named in this final order.

The device is assigned the generic name strabismus detection device, and it is identified as a prescription device designed to simultaneously illuminate

both eyes with polarized light for automated detection of strabismus by analyzing foveal birefringence properties.

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—STRABISMUS DETECTION DEVICE RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Mitigation measures
Diagnostic risks (false positives, false negatives, no output)	• Clinical performance testing; • Non-clinical performance testing; • Software verification, validation and hazard analysis; and • Labeling.
Electromagnetic interference with other devices	• Electromagnetic compatibility (EMC) testing; and • Labeling.
Electrical shock	• Electrical safety testing; and • Labeling.
Ocular Light Toxicity	• Optical radiation safety testing; • Software verification, validation and hazard analysis; and • Labeling.
Use Error	• Labeling.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Strabismus detection devices are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

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), 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 strabismus detection device 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 refers 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; the collections of information in 21 CFR part 820, regarding the quality 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 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for 21 CFR part 886 continues to read as follows:

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

■ 2. Add § 886.1342 to subpart B to read as follows:

§ 886.1342 Strabismus detection device.

(a) *Identification.* A strabismus detection device is a prescription device designed to simultaneously illuminate both eyes with polarized light for automated detection of strabismus by analyzing foveal birefringence properties.

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

(1) Clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use. Testing must be conducted in a representative patient population and clinical setting for the indicated use. Demonstration of clinical performance must include assessment of sensitivity and specificity compared to a clearly defined reference standard (*e.g.,* comprehensive ophthalmological examination comprises age-appropriate visual acuity testing, examination of the external ocular adnexae and orbit, anterior segment evaluation, extraocular motility evaluation, assessment of stereopsis, cycloplegic refraction, and dilated fundus examination).

(2) Non-clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use. The following technical characteristics must be evaluated:

(i) Verification of lowest detectable amount of deviation; and

(ii) Validation of the accuracy and precision at the lowest detectable amount of deviation.

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

(4) Optical radiation safety testing must demonstrate the device is safe per the directions for use.

(5) Performance testing must demonstrate the electromagnetic compatibility of the device.

(6) Performance testing must demonstrate the electrical safety of the device.

(7) Labeling must include the following:

(i) Summaries of non-clinical and clinical performance testing;

(ii) Instructions on how to correctly use and maintain the device;

(iii) Instructions and explanation of all user-interface components; and

(iv) Information related to electromagnetic compatibility and optical radiation classification.

Dated: September 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22801 Filed 9–21–16; 8:45 am]

BILLING CODE 4164–01–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 240

USAID Sovereign Loan Guarantees—Standard Terms and Conditions

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This regulation prescribes the procedures and standard terms and conditions applicable to loan guarantees to be issued for the benefit of Ukraine.

DATES: Effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: D. Bruce McPherson, Office of the General Counsel, U.S. Agency for International Development, Washington, DC 20523–6601; tel. 202–712–1611, fax 202–216–3055.

SUPPLEMENTARY INFORMATION: Pursuant to the authority of section 7034(o)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113), the United States of America, acting through the U.S. Agency for International Development, may issue certain loan guarantees applicable to sums borrowed by Ukraine (the ''Borrower''), not exceeding an aggregate total of U.S. $1 billion in principal amount. Upon issuance, the loan guarantees shall ensure the Borrower's repayment of 100% of principal and interest due under such borrowings and the full faith and credit of the United States of America shall be pledged for the full payment and performance of such guarantee obligations.

This rulemaking document is not subject to rulemaking under 5 U.S.C. 553 or to regulatory review under Executive Order 12866 because it involves a foreign affairs function of the United States. The provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) do not apply.

List of Subjects in 22 CFR Part 240

Foreign aid, Foreign relations, Guaranteed loans, Loan programs-foreign relations.

Authority and Issuance

■ Accordingly, part 240 is added to title 22, chapter II, of the Code of Federal Regulations, to read as follows:

PART 240—SOVEREIGN LOAN GUARANTEE—STANDARD TERMS AND CONDITIONS

Sec.

Authority: Section 7034(o)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113).

§ 240.1 Purpose.

The purpose of the regulations in this part is to prescribe the procedures and standard terms and conditions applicable to loan guarantees issued for the benefit of the Borrower, pursuant to section 7034(o)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113) (the ''Authority''). The loan guarantees will be issued as provided herein pursuant to a Loan Guarantee Agreement signed on June 3, 2016, between the United States of America and Ukraine (the ''Loan Guarantee Agreement''). The loan guarantee will apply to sums borrowed during a period beginning on the date that the Loan Guarantee Agreement enters into force and ending thirty days after such date, not exceeding an aggregate total of one billion United States Dollars ($1,000,000,000) in principal amount. The loan guarantees shall ensure the Borrower's repayment of 100% of principal and interest due under such borrowings. The full faith and credit of the United States of America is pledged for the full payment and performance of such guarantee obligations.

§ 240.2 Definitions.

Wherever used in the standard terms and conditions set out in this part:

Applicant means a Noteholder who files an Application for Compensation with USAID, either directly or through the Fiscal Agent acting on behalf of a Noteholder.

Application for Compensation means an executed application in the form of appendix A to this part which a Noteholder, or the Fiscal Agent on behalf of a Noteholder, files with USAID pursuant to § 240.8.

Borrower means Ukraine.

Business Day means any day other than a day on which banks in New York, NY are closed or authorized to be closed or a day which is observed as a federal holiday in Washington, DC, by the United States Government.

Date of Application means the date on which an Application for Compensation is actually received by USAID pursuant to § 240.15.

Defaulted Payment means, as of any date and in respect of any Eligible Note, any Interest Amount and/or Principal Amount not paid when due.

Eligible Note(s) means [a] Note[s] meeting the eligibility criteria set out in § 240.4.

Fiscal Agency Agreement means the agreement among USAID, the Borrower and the Fiscal Agent pursuant to which the Fiscal Agent agrees to provide fiscal agency and trust services in respect of the Note[s], a copy of which Fiscal Agency Agreement shall be made available to Noteholders upon request to the Fiscal Agent.

Fiscal Agent means the bank or trust company or its duly appointed successor under the Fiscal Agency Agreement which has been appointed by the Borrower with the consent of USAID to perform certain fiscal agency and trust services for specified Eligible Note[s] pursuant to the terms of the Fiscal Agency Agreement.

Further Guaranteed Payments means the amount of any loss suffered by a Noteholder by reason of the Borrower's failure to comply on a timely basis with any obligation it may have under an Eligible Note to indemnify and hold harmless a Noteholder from taxes or governmental charges or any expense arising out of taxes or any other governmental charges relating to the Eligible Note in the country of the Borrower.

Guarantee means the guarantee of USAID pursuant to the Authority.

Guarantee Payment Date means a Business Day not more than three (3) Business Days after the related Date of Application.

Interest Amount means for any Eligible Note the amount of interest accrued on the Principal Amount of