



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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on June 8, 2016.

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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)	<ul style="list-style-type: none"> • Clinical performance testing; • Non-clinical performance testing; • Software verification, validation and hazard analysis; and • Labeling
Electromagnetic interference with other devices	<ul style="list-style-type: none"> • Electromagnetic compatibility (EMC) testing; and • Labeling
Electrical shock	<ul style="list-style-type: none"> • Electrical safety testing; and • Labeling
Ocular Light Toxicity	<ul style="list-style-type: none"> • Optical radiation safety testing; • Software verification, validation and hazard analysis; and • Labeling
Use Error	<ul style="list-style-type: none"> • 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.

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