Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ 2. Add § 876.5960 to subpart F to read as follows:

§ 876.5960 Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions.

(a) *Identification.* A computerized behavioral therapy device for treating symptoms of gastrointestinal conditions is a prescription device intended to provide a computerized version of condition-specific therapy as an adjunct to standard of care treatments to patients with gastrointestinal conditions.

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

(1) Clinical data must be provided to fulfill the following:

(i) Describe a model of therapy for the indicated gastrointestinal conditions;

(ii) Validate the model of therapy as implemented by the device using a clinically defined endpoint; and

(iii) Evaluate all adverse events.

(2) Software must be described in detail in the software requirements specification and software design specification. Software verification, validation, and hazard analysis must be performed. Software documentation must demonstrate that the device effectively implements the behavioral therapy model.

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Labeling:

(i) Labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the device is not intended for use in lieu of a standard therapeutic intervention or to represent a substitution for the patient's medication;

(iv) Patient and physician labeling must include a warning to seek medical care if a patient has feelings or thoughts of harming themselves or others; and

(v) Physician and patient labeling must include a summary of the clinical testing with the device.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01048 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2022–N–3256]

Medical Devices; Ophthalmic Devices; Classification of the Intense Pulsed Light Device for Managing Dry Eye

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the intense pulsed light device for managing dry eye into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intense pulsed light device for managing dry eye's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 20, 2023. The classification was applicable on February 23, 2021.

FOR FURTHER INFORMATION CONTACT: Arkady Kaplan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1568, Silver Spring, MD 20993–0002, 301–796–6365, *Morris.Kaplan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the intense pulsed light device for managing dry eye as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under

section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 20, 2020, FDA received Lumenis's request for De Novo classification of the Lumenis Stellar M22. 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.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 23, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 886.5201.[1] We have named the generic type of device intense pulsed light device for managing dry eye, and it is identified as a prescription device intended for use in the application of intense pulsed light therapy to the skin. The device is used in patients with dry eye disease due to meibomian gland dysfunction, also known as evaporative dry eye or lipid deficiency dry eye.

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—INTENSE PULSED LIGHT DEVICE FOR MANAGING DRY EYE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Tissue damage due to overheating	Thermal safety assessment, Software verification, validation, and hazard analysis, and Labeling.
Tissue damage or loss of vision due to light radiation	Clinical performance testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock or burn	Thermal safety assessment, Electrical safety testing, Software verification, validation, and hazard analysis, and Labeling.
Interference with other devices	Electromagnetic compatibility testing; Software verification, validation, and hazard analysis; and Labeling.
Pain or discomfort	Clinical performance testing, and Labeling.
Failure to mitigate dry eye signs and/or symptoms	Clinical performance testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, intense pulsed light device for managing dry eye is/are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; 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 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

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

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

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

■ 2. Add § 886.5201 to subpart F to read as follows:

§ 886.5201 Intense pulsed light device for managing dry eye.

(a) *Identification.* An intense pulsed light device for managing dry eye is a prescription device intended for use in the application of intense pulsed light therapy to the skin. The device is used in patients with dry eye disease due to meibomian gland dysfunction, also known as evaporative dry eye or lipid deficiency dry eye.

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

(1) Clinical performance testing must evaluate adverse events and improvement of dry eye signs and symptoms under anticipated conditions of use.

(2) Thermal safety assessment in a worst-case scenario must be performed to validate temperature safeguards.

(3) Performance testing must demonstrate electrical safety and electromagnetic compatibility (EMC) of the device in the intended use environment.

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

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

(6) Physician and patient labeling must include:

(i) Device technical parameters;

(ii) A summary of the clinical performance testing conducted with the device;

(iii) A description of the intended treatment area location;

(iv) Warnings and instructions regarding the use of safety-protective eyewear for patient and device operator;

(v) A description of intense pulse light (IPL) radiation hazards and protection for patient and operator;

(vi) Instructions for use, including an explanation of all user interface components; and

(vii) Instructions on how to clean and maintain the device and its components.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01049 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000, 1002, 1010, 1020, 1030 and 1050

[Docket No. FDA–2018–N–3303]

RIN 0910–AH65

Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is amending and repealing parts of the radiological health regulations covering recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products. The Agency is taking this action to clarify and update the regulations to reduce regulatory requirements that are outdated and duplicate other means to better protect the public health against harmful exposure to radiation emitting electronic products and medical devices.

DATES: This rule is effective February 21, 2023.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert Ochs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3680, Silver Spring, MD 20993, 301–796–6661, email: *Robert.Ochs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

This final rule amends and repeals certain regulations for radiation emitting electronic products and medical devices because the FDA has identified the regulations as being outdated and duplicative of other means for reducing radiation exposure to the public. The Agency is updating the regulations to amend or repeal regulations that are outdated and otherwise clarify requirements for protecting the public health against radiation exposure from specific electronic products and medical devices. The regulations being finalized for amendment or repeal are the radiation protection recommendations for specific uses, records and reporting requirements for electronic products, applications for variances, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products.

B. Summary of the Major Provisions of the Final Rule

This final rule updates FDA's radiological health regulations to amend or repeal the following provisions:

- Repeal the radiation protection recommendations that have become outdated and unnecessary;
- Removing or reducing some of the annual reports and test record