



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2016-N-1268]

Medical Devices; Ophthalmic Devices; Classification of the Diurnal Pattern Recorder System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the diurnal pattern recorder system 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 diurnal pattern recorder system'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 March 4, 2016.

FOR FURTHER INFORMATION CONTACT: Alexander Beylin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2404, Silver Spring, MD 20993-0002, 301-796-6463.

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 April 28, 2014, Sensimed AG submitted a request for classification of the SENSIMED Triggerfish<sup>®</sup> 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). 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 March 4, 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 886.1925.

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

The device is assigned the generic name diurnal pattern recorder system, and it is identified as a nonimplantable, prescription device incorporating a telemetric sensor to detect changes in ocular dimension for monitoring diurnal patterns of intraocular pressure (IOP) fluctuations.

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

Table 1.--Diurnal Pattern Recorder System Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Ocular Adverse Events: <ul style="list-style-type: none"> <li>• Hyperemia</li> <li>• Punctate keratitis</li> <li>• Discomfort</li> <li>• Dry eye--dry sensation in the eye where the sensor is placed</li> <li>• Foreign body sensation--gritty feeling</li> <li>• Itching, burning</li> <li>• Swelling of eyelids</li> <li>• Pink eye</li> <li>• Excessive watering, unusual secretions or redness of the eye</li> <li>• Eye pain or irritation</li> <li>• Eye injury</li> </ul>	Clinical testing Biocompatibility evaluation Labeling
Infection	Sterilization validation Labeling
Adverse Tissue Reaction	Biocompatibility evaluation Labeling
Software Malfunction	Software verification, validation, and hazard analysis
Hardware Malfunction	Nonclinical testing
Use Error (e.g., improper fit, device manipulation)	Clinical testing Labeling
Electromagnetic Interference with Other Devices	Electromagnetic compatibility (EMC) and electromagnetic interference (EMI) testing Labeling
Electrical Malfunction (e.g., shock, battery-related issues)	Electrical safety testing Labeling
Measurement Noise or Artifact Leading to Incorrect Graphical Representation of Variation	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.

Diurnal pattern recorder systems are not safe for use except under the supervision of a practitioner licensed by law to direct the use 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) 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 diurnal pattern recorder system 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 parts 801 and 809, 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. DEN140017: De novo request per 513(f)(2) from Sensimed AG, dated April 28, 2014.

#### 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 part 886 continues to read as follows:

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

2. Add § 886.1925 to subpart B to read as follows:

§ 886.1925 Diurnal pattern recorder system.

(a) Identification. A diurnal pattern recorder system is a nonimplantable, prescription device incorporating a telemetric sensor to detect changes in ocular dimension for monitoring diurnal patterns of intraocular pressure (IOP) fluctuations.

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

(1) Clinical performance data must demonstrate that the device and all of its components perform as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

- (i) Ability of the device to detect diurnal changes.
- (ii) Tolerability of the system at the corneoscleral interface in the intended use population.

(2) Nonclinical testing must validate measurements in an appropriate nonclinical testing model to ensure ability to detect changes in intraocular pressure.

(3) Patient-contacting components must be demonstrated to be biocompatible.

(4) Any component that is intended to contact the eye must be demonstrated to be sterile throughout its intended shelf life.

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

(6) Performance testing must demonstrate the electromagnetic compatibility and electromagnetic interference of the device.

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

(8) Labeling must include the following:

- (i) Warning against activities and environments that may put the user at greater risk.
- (ii) Specific instructions for the safe use of the device, which includes:
  - (A) Description of all device components and instructions for assembling the device;
  - (B) Explanations of all available programs and instructions for their use;
  - (C) Instructions and explanation of all user-interface components;
  - (D) Instructions on all safety features of the device; and
  - (E) Instructions for properly maintaining the device.

(iii) A summary of nonclinical testing information to describe EMC safety considerations.

(iv) A summary of safety information obtained from clinical testing.

(v) Patient labeling to convey information regarding appropriate use of device.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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