DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 21, 2016

SENSIMED AG
% Ms. Marcy Moore
MMP Medical Associates, LLC
131 Kelekent Lane
Cary, NC 27518

Re: DEN140017
SENSIMED Triggerfish®
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 886.1925
Regulation Name: Diurnal Pattern Recorder System
Regulatory Classification: Class II
Product Code : PLZ
Dated: April 28, 2014
Received: May 6, 2014

Dear Ms. Moore:

This letter corrects our classification order dated March 4, 2016.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the SENSIMED Triggerfish, a prescription device under 21 CFR Part 801.109 that is indicated as follows:

> *The SENSIMED Triggerfish® is a prescription device indicated to detect the peak patterns of variation in intraocular pressure over a maximum period of 24 hours to identify the window of time to measure intraocular pressure by conventional clinical methods. The SENSIMED Triggerfish® is indicated for patients 22 years of age and older.*

FDA concludes that this device should be classified into class II. This order, therefore, classifies the SENSIMED Triggerfish, and substantially equivalent devices of this generic type, into class II under the generic name, Diurnal Pattern Recorder System.

FDA identifies this generic type of device as:

> **Diurnal Pattern Recorder System.** A diurnal pattern recorder system is a non-implantable, prescription device incorporating a telemetric sensor to detect changes in ocular dimension for monitoring diurnal patterns of intraocular pressure (IOP) fluctuations.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not

substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On May 6, 2014, FDA received your *de novo* requesting classification of the SENSIMED Triggerfish® into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SENSIMED Triggerfish® into class I or II, it is necessary that the proposed class have sufficient regulatory 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 *de novo* request**,** FDA has determined that the SENSIMED Triggerfish® indicated as follows:

> *The SENSIMED Triggerfish® is a prescription device indicated to detect the peak patterns of variation in intraocular pressure over a maximum period of 24 hours to identify the window of time to measure intraocular pressure by conventional clinical methods. The SENSIMED Triggerfish® is indicated for patients 22 years of age and older.*

can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Ocular Adverse Events • Hyperemia • Punctate keratitis • Discomfort • Dry eye –dry sensation in the eye where the sensor is placed • Foreign body sensation – gritty feeling • Itching, burning • Swelling of eyelids • Pink eye • Excessive watering, unusual secretions or redness of the eye • Eye pain or irritation • Eye injury	Clinical Testing Biocompatibility Evaluation Labeling

Identified Risk	Mitigation Measure
Infection	Sterilization Validation Labeling
Adverse Tissue Reaction	Biocompatibility Evaluation Labeling
Software Malfunction	Software Verification, Validation, and Hazard Analysis
Hardware Malfunction	Non-clinical 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

In combination with the general controls of the FD&C Act, the Diurnal Pattern Recorder System is subject to the following special controls:

1. Clinical performance data must demonstrate that the device and all if its components perform as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:
    a. ability of the device to detect diurnal changes
    b. tolerability of the system at the corneoscleral interface in the intended use population.

2. Non-clinical testing must validate measurements in an appropriate non-clinical 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:
    - Warning against activities and environments that may put the user at greater risk.

- Specific instructions for the safe use of the device, which includes:
  - Description of all device components and instructions for assembling the device;
  - Explanations of all available programs and instructions for their use;
  - Instructions and explanation of all user-interface components;
  - Instructions on all safety features of the device; and
  - Instructions for properly maintaining the device.
- A summary of non-clinical testing information to describe EMC safety considerations.
- A summary of safety information obtained from clinical testing.
- Patient labeling to convey information regarding appropriate use of device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.
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 type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Diurnal Pattern Recorder System they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Alexander Beylin, Ph.D. at (301) 796-6620.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health