May 21, 2020

Tear Film Innovations, Inc.
Neal Hartman
Sr. Director, Regulatory Affairs/Quality Assurance
5924 Balfour Court, Suite 100
Carlsbad, CA 92008

Re: K200400
Trade/Device Name: Systane iLux$^2$
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ, HKI
Dated: April 15, 2020
Received: April 16, 2020

Dear Neal Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products

(see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200400

Device Name
Systane iLux$^2$

Indications for Use *(Describe)*

The Systane iLux$^2$ is indicated for the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY – K200400

## Submitter Information


| | |
|---|---|
| Company Name: | Tear Film Innovations, Inc. |
| Company Address: | 5924 Balfour Court, Suite 100<br>Carlsbad, CA 92008 |
| Company Phone: | (760) 444-9555 |
| Company Facsimile: | (442) 244-4696 |
| Contact Person: | Neal Hartman<br>Sr. Director of Regulatory Affairs/Quality Assurance<br>nhartman@tearfilm.com |
| Date: | May 20, 2020 |


## Device Identification

| | |
|---|---|
| Device Trade Name: | Systane iLux$^2$ |
| Common Name: | N/A |

| | | |
|---|---|---|
| Classification Names | Eyelid Thermal Pulsation System | Camera, Ophthalmic, Ac-Powered |
| Regulations | 886.5200 | 886.1120 |
| Device Class | 2 | 2 |
| Product Codes | ORZ | HKI |
| Advisory Panel | Ophthalmic | Ophthalmic |

## Identification of Predicate Devices

The System Device is substantially equivalent to the following device:

| Device Name | Classification Regulation | Product Code | 510(K) Number | Clearance Date |
|---|---|---|---|---|
| iLux System | 886.8200 – Eyelid Thermal Pulsation System | ORZ | K172645 | 12/26/2017 |

## Device Description

The Subject Device is indicated for the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with evaporative dry eye. The device can capture images and videos of the eyelid margin and meibomian glands. These images can be use in meibography (i.e., visual morphology of meibomian glands).

In treatment mode, light-based heat is used to warm the eyelid tissue to a target range of 38-44 ºC to melt the meibum blocking the gland orifices. The Eye Care Professionals (ECP) can apply compression to the eyelid to express the melted meibum through the orifices. At all times, the amount of the heat and pressure applied is under direct control of the ECP who monitors the response of the glands and the comfort of the patient. The inner eyelid temperature is displayed during the treatment process. The source of heating is lime-green and IR optical radiation produced by LEDs incorporated in the Instrument. Images and video can be captured during treatment.

In meibography mode, infrared (IR) light is used in the visualization of meibomian gland morphology. Images can be captured with IR or white light. Video is captured only with white light.

The Subject Device consists of the following:

- Reusable, Hand-Held Instrument – Incorporates hardware, software, and mechanics to facilitate treatment and imaging.

  The Instrument incorporates an LCD touchscreen user interface that is used to view the eyelid margin as well as provides instructions to the ECP during use. Selections can be made through the user interface and images/video can be viewed.

  The Instrument is powered by a rechargeable lithium ion battery.

- Docking Station – Is used to charge the Instrument's internal battery and transfer images/video to an external monitor or PC.

- AC Power Supply – Transfer electricity for the AC electrical outlet to the Docking Station.

- Photography Tip (Photo Tip) – Is reusable, up to a specified number of attachments, and when coupled with the Instrument it is used to capture images and video. There is electronics in the Photo Tip that interfaces with the Instrument. The Photo Tip is positioned on the cheek bone or eyebrow. The patient contacting material is biocompatible.

- Smart Tip Patient Interface (Smart Tip) – Is sterile and single-use that when coupled with the Instrument treatment can be provided. There is electronics in the Smart Tip that interfaces with the Instrument. A feature of the Smart Tip is positioned behind the eyelid during the treatment process. The patient contacting material is biocompatible.

- USB & HMDI Cable – Attaches Docking Station to external monitor/PC.

**Indications for Use**

The Systane iLux$^2$ is indicated for the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with

evaporative dry eye, and to capture/store digital images and video of the meibomian glands

## Comparison of Technological Characteristics with Predicate and Reference Devices

| Comparison Feature | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| Device name | Systane iLux$^2$ | iLux System | LipiScan Dynamic Meibomian Imager |
| Manufacturer | Tear Film Innovations, Inc. | Tear Film Innovations, Inc. | TearScience, Inc (Johnson & Johnson) |
| Device classification | 2 | 2 | 2 |
| Product Code | ORZ | ORZ | HKI |
| Indications for Use | The Systane iLux$^2$ is indicated for the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands | The iLux System is indicated for the application of localized heat and pressure therapy in adult patients with chronic disease of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye. | LipiScan Dynamic Meibomian Imager is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands. |
| System components | • Reusable Handheld Instrument<br>• Smart Tip Patient Interface<br>• Photography Tip<br>• Charging/Image Transfer Station | • Reusable Handheld Instrument<br>• Smart Tip Patient Interface<br>• Charging Station | • Computer system<br>• Electronics<br>• Chin and forehead rest<br>• Camera and attached lens<br>• Illuminator<br>• Touchscreen display<br>• Handheld near-infrared (IR) lid everter<br>• Power supply |
| Patient contact system component | • Smart Tip Patient Interface<br>• Photography Tip | Smart Tip Patient Interface | • Chin and forehead rest<br>• Handheld near-infrared (IR) lid everter |
| Single use | Smart Tip Patient Interface | Smart Tip Patient Interface | N/A |
| Sterile | Smart Tip Patient Interface | Smart Tip Patient Interface | N/A |
| Method of sterilization, SAL | Ethylene Oxide, SAL $10^{-6}$ | Ethylene Oxide, SAL $10^{-6}$ | N/A |
| Packaging, Sterile Barrier | Thermoform Tray/Tyvek Lidding Stock | Tyvek Pouch | N/A |
| System control component | Reusable Handheld Instrument | Reusable Handheld Instrument | Window based PC |
| Software | Yes | Yes | Yes |
| Operating orientation | Handheld | Handheld | Stationary |
| User Interface | • Touchscreen OLED Display<br>• Control Button<br>• Smart Tip Patient Interface | • Control Button<br>• Smart Tip Patient Interface | • Chin and forehead rest<br>• Touchscreen display |

| Comparison Feature | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| Device name | Systane iLux$^2$ | iLux System | LipiScan Dynamic Meibomian Imager |
| | • Photography Tip | | • Handheld near-infrared (IR) lid everter |
| System's component for viewing glands | OLED Display | Magnifying Lens | Integrated Monitor |
| Tip Attachment to Handheld Instrument | Mechanical (identical to Predicate) | Mechanical | N/A |
| Patient interface during treatment | Smart Tip Patient Interface (identical to Predicate) | Smart Tip Patient Interface | N/A |
| Treatment of upper and lower eyelids | Sequential | Sequential | N/A |
| Treatment Time | Typically, 8-12 minutes | Typically, 8-12 minutes | N/A |
| Safety-Related Power/ Heat Management | Dedicated Processor | Dedicated FPGA | N/A |
| Heat Source | LEDs (lime-green and IR wavelengths) with reflective shroud (identical to Predicate) | LEDs (lime-green and IR wavelengths) with reflective shroud | N/A |
| Rate of heating (time to target temperature) | 15 to 50 seconds | 15 to 50 seconds | N/A |
| Temperature, accuracy | +/- 1.0° | +/- 1.0° | N/A |
| Target temperature range | 38 to 44 ºC | 38 to 44 ºC | N/A |
| Maximum Inner Eyelid Surface temperature limit | 44 ºC | 44 ºC | N/A |
| Maximum Outer Eyelid Surface temperature limit | 45 ºC | 45 ºC | N/A |
| Compression Mechanism | Mechanical (identical to Predicate) | Mechanical | N/A |
| Pressure Control | Manual via control button (identical to Predicate): Eye Care Professional determines (based on patient feedback and direct viewing of glands) | Manual via control button: Eye Care Professional determines (based on patient feedback and direct viewing of glands) | N/A |
| Pressure type | Compression, repeated as necessary | Compression, repeated as necessary | N/A |
| Patient Interface during Imaging | Photography Tip | N/A | • Chin and forehead rest<br>• Handheld near-infrared (IR) lid everter |
| Imaging Controls | Touchscreen display | N/A | Touchscreen display |

| Comparison Feature | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| Device name | Systane iLux$^2$ | iLux System | LipiScan Dynamic Meibomian Imager |
| Illumination, Imaging | White light or infrared (IR) | No | Infrared (IR) |
| Ability to capture images | Yes, Photography Tip use to maintain focal point | No | Yes |
| Meibography imaging | Yes, Photography Tip use to maintain focal point | No | Yes |
| Ability to capture video | Yes, Photography Tip use to maintain focal point | No | No |
| Resolution, Onboard | 240 x 170 (Portrait)<br>320 x 240 (Landscape) | N/A | Unknown |
| Resolution, External | 1080p (Video)<br>2304 x 1536 (Images) | N/A | Unknown |
| Image Transfer Method | Docking station-to-HDMI cable-to-external monitor<br>Docking station-to-USB cable-to-PC<br>SD card-to-PC | N/A | HDMI cable to monitor<br>USB 2.0 |
| Power Source/ Charging | Batteries, DC/ Charging/Image Transfer station via AC power adapter | Batteries, DC/ charging station via AC power adapter | AC |
| Installation required | No | No | No |

## Summary of Testing Performed

A program of design verification and validation testing was performed that includes the following:

- Biocompatibility
- Sterility and EO Residual
- Packaging Integrity (i.e., Sterile Barrier)
- Transportation
- Optical Radiation Safety
- Electromagnetic Compatibility and Electrical Safety
- Stability/Shelf-Life
- Performance/Functionality/Safety
- Software
- Simulated Use (Human Factors Evaluation)

Results of the evaluations demonstrate that the Subject Device met the safety and performance requirements as it relates to its indication for use.

## Conclusions Drawn from Nonclinical Evaluation

The results of the evaluation demonstrate that the Subject Device is substantially equivalent to the Predicate and Reference Devices as it pertains to the indications for use and device performance.