DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 14, 2016

Tearscience, Inc.
% Dr. Christy Coleman
Vice President, Clinical, Quality and Regulatory Affairs
5151 McCrimmon Pkwy., Suite 250
Morrisville, North Carolina 27650

Re: K152869
Trade/Device Name: Lipiview II Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Opthalmic Camera
Regulatory Class: Class II
Product Code: HKI, HJO
Dated: December 8, 2015
Received: December 9, 2015

Dear Dr. Coleman:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152869

Device Name
LipiView® II Ocular Surface Interferometer

Indications for Use *(Describe)*
The LipiView II Ocular Surface Interferometer is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of:

• Specular (interferometric) observations of the tear film. Using these images, LipiView® II measures the absolute thickness of the tear film lipid layer.
• Meibomian glands under near-infrared (NIR) illumination
• The ocular surface and eyelids under white illumination

All of these image types can be photographically documented and visually monitored.

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.

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510(k) SUMMARY

PREPARATION DATE:	September 29, 2015
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 467-4007 Fax: (919) 467-3300
CONTACT PERSON:	Christy Coleman, OD, MPH Vice President, Clinical, Quality and Regulatory Affairs
DEVICE TRADE NAME:	LipiView® II Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II; 21 CFR 886.1120 and 21 CFR 886.1850
PRODUCT CODE:	HKI, HJO
PREDICATE DEVICES:	**PRIMARY: LipiView® Ocular Surface Interferometer** Class II under 21 CFR 886.1120 and 21 CFR 886.1850; Product Code HKI, HJO; Applicant: TearScience, Inc.; Originally cleared under K091935 on October 23, 2009; Expanded Indications for Use cleared under K122481 on December 31, 2012 **SECONDARY: Optomed Smartscope M5 Digital Camera** Class II under 21 CFR 886.1120; Product Code HKI; Applicant: Optomed Oy.; Cleared under K132186 on December 18, 2013

DEVICE DESCRIPTION:

The LipiView® II Ocular Surface Interferometer is a bench-top device used as an ophthalmic camera for imaging the lipid layer of the tear film, meibomian glands, ocular surface and eyelids. There are three imaging modes: Lipid, Gland and Ocular. LipiView II contains a computer system and electronics, two position chin and forehead rest, camera and lens, motion stage, illuminator and touch screen display. LipiView II includes pushbutton controls and handheld near-infrared lid everter for gland imaging.

In the Lipid Imaging mode, LipiView II operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display, in a printed report, or captured on video and exported to USB-attached storage or a mapped network drive.

In the Gland Imaging Mode, LipiView II uses near infrared (NIR) illumination and an NIR-sensitive camera mounted on a motion control system to image the meibomian glands. The tissue between the meibomian glands and the surface of the eyelid are transparent to NIR light. The glands reflect NIR wavelengths, allowing them to be imaged.

In the Ocular Imaging mode, LipiView II captures high-resolution still images or video to record relevant findings on the ocular surface and/or eyelids. The images can be taken using room light only or the device's built-in white light.

The LipiView II Interferometer does not provide a diagnosis. The device has no treatment or no life-sustaining functions, and presents no potential for serious risk to the health, welfare or safety of patients.

INTENDED USE:

The LipiView® II Ocular Surface Interferometer is intended to image the eye and surrounding area. The LipiView II Interferometer is a prescription device for use by a physician during an in-office exam.

Indications for Use: The LipiView II Ocular Surface Interferometer is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of:

- Specular (interferometric) observations of the tear film. Using these images, LipiView® II measures the absolute thickness of the tear film lipid layer.
- Meibomian glands under near-infrared (NIR) illumination
- The ocular surface and eyelids under white illumination

All of these image types can be photographically documented and visually monitored.

As an ophthalmic camera, LipiView II has the same intended use to image the eye and surrounding area as the predicate devices, LipiView Interferometer (K091935, K122481) and Optomed Smartscope M5 Digital Camera (K132186). The Indications for Use for LipiView II are similar to the predicate LipiView device, except that the parts of the eye and surrounding area being imaged have been expanded to include the meibomian glands, ocular surface and eyelids. The expanded Indications for Use do not alter the intended use of the LipiView II Interferometer. LipiView II does not provide a diagnosis, and imaging other parts of the eye does not affect the safety and effectiveness of the device.

TECHNOLOGICAL CHARACTERISTICS:

The LipiView II Interferometer has the same fundamental scientific technology as the predicate devices. As summarized below, most of the technological characteristics of the LipiView II Interferometer remain unchanged from the predicate LipiView device. In addition, LipiView II and Optomed Smartscope M5 with optics module ES2 use similar visible and infrared LED illumination to image the eye. A comparison of the technology between LipiView II and each of the predicate devices is summarized below.

Comparison to LipiView Interferometer: The predicate LipiView device and LipiView II have the same principle of operation as an ophthalmic camera to image the eye and for specular observations of the tear film using white light interferometry. Both bench-top devices have similar overall dimensions and components, including computer system and electronics, chin and forehead rest, camera and lens, motion stage, illuminator and touch screen display. Both devices may be used with off-the-shelf USB accessories and operate wirelessly with networks.

Similar design features include: adjustable forehead and chin rest with the same patient contact material and disinfection method; digital video camera adjusted using a motion stage; white light Class I LED illuminator; and a visible LED fixation light. Both devices comply with ISO15004-2 standard for light hazard protection. Both devices have an AC power source in compliance with ANSI/IEC 60601 standards for electrical safety and electromagnetic compatibility (EMC). Both devices have flame retardant materials per UL 94V-1 standard. Both devices have ambient temperature of parts of device held by operator or accessible to patient in compliance with ISO 15004-1 standard.

The software on both devices runs on a Microsoft Windows-based operating system with a touchscreen display graphical user interface. Similar software design features include: password-protected user login; patient entry into a database; real-time video display to acquire and view images; touchscreen user controls for camera and video playback; image acquisition process with storage of lossless AVI format video images; printed or saved reports; and export of images to USB external media or electronic medical record system via wireless network. In addition, both devices use the same tear film lipid layer image processing for analysis and measurement of the lipid layer thickness.

Different design features include new hardware components in LipiView II: pushbutton controls, a two-position adjustable chin rest, a high definition camera, surface NIR illumination, and a handheld NIR lid everter. These design changes are to support imaging other parts of the eye and surrounding area, such as the meibomian glands. The primary software changes in LipiView II are an update to the Windows-based operating system, new graphical user interface appearance; and new meibomian gland imaging and ocular imaging functionality. Other minor hardware and software changes relative to the predicate LipiView device were made for user convenience or product enhancement.

Comparison to Optomed M5 Digital Camera: The Optomed M5 Digital Camera with ES2 optics module and LipiView II have the same principle of operation as an ophthalmic camera for digital imaging of the eye. Both devices have a camera, lens, visible and infrared LED illumination and visible LED fixation light. Both devices

comply with ISO15004-2:2007 standard for light hazard protection. Both devices have a power source in compliance with ANSI/IEC 60601-1-1 and 60601-1-2 standards for electrical safety and EMC. Also, both devices have display systems to view images and both provide image storage capability on external media.

LipiView II is a bench-top device with a computer system, software and a touchscreen display graphical user interface. Conversely, Optomed Smartscope M5 with optic module ES2 consists of a camera handset, attachable ophthalmic lens, cradle for charging and image transfer to a PC by USB connection. LipiView II has an integrated chin rest to support the patient's head, whereas, Optomed Smartscope utilizes an adapter to a slit lamp biomicroscope, which has support for the patient's head.

PERFORMANCE TESTING:

Performance testing demonstrates that the design changes in LipiView II do not raise new questions of safety and effectiveness, and LipiView II is substantially equivalent to the predicate devices.

- Usability testing and software validation demonstrate that LipiView II is as safe and as effective as the predicate devices in the intended use to image the eye and surrounding area, including meibomian glands, ocular surface and eyelids.
- As for the predicate devices, LipiView II meets the standards for light hazard protection, electrical safety and electromagnetic compatibility and material flammability. Therefore, the use of near infrared illumination does not raise new safety or effectiveness questions.
- The new hardware features in LipiView II, including two-position chin rest, high definition camera, NIR illumination and handheld NIR lid everter, meet all design requirements for safety and performance, and therefore, do not adversely affect safety and effectiveness as compared to the predicate device.

CONCLUSIONS:

The LipiView II Ocular Surface Interferometer has the same intended use and the same fundamental scientific technology as the predicate devices. The expanded Indications for Use for LipiView II relative to the predicate devices do not alter the intended use and do not affect safety and effectiveness of the device. Performance testing demonstrates the LipiView II Interferometer is substantially equivalent in intended use and technological characteristics to the predicate devices. The technology differences do not raise new questions of safety and effectiveness, and do not adversely affect safety and effectiveness of the device. Based on overall design verification and validation and bench performance testing, LipiView II is at least as safe and effective as the predicate devices.

TABLE 5-1. PREDICATE DEVICE COMPARISON TABLE

Comparison Feature	LipiView II Interferometer	Predicate LipiView Interferometer (K091935 and K122481)	Optomed Smartscope M5 Digital Camera (K132186)
Intended Use	Intended to take photographs of the eye and the surrounding area	Intended to take photographs of the eye and the surrounding area	Intended to take photographs of the eye and the surrounding area
Indications for Use	The LipiView II Ocular Surface Interferometer is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of: • Specular (interferometric) observations of the tear film. Using these images, LipiView II measures the absolute thickness of the tear film lipid layer. • Meibomian glands under near-infrared (NIR) illumination. • The ocular surface and eyelids under white illumination. All of these image types can be photographically documented and visually monitored.	The LipiView Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate, and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.	Optomed Smartscope M5 with optics module ES2 is intended to capture images and video of the surface of the human eye and surrounding areas.
Rx only/OTC	Prescription Device	Prescription Device	Prescription Device
Method of Operation Ophthalmic Imaging	Ophthalmic camera with digital imaging	Ophthalmic camera with digital imaging	Ophthalmic camera with digital imaging
Method of Operation Specular Observation of Tear Film	Tear film images and lipid layer thickness measurement based on specular reflection using white light interferometry	Tear film images and lipid layer thickness measurement based on specular reflection using white light interferometry	None
Illumination Source	• Visible White Class I LED illumination • Visible LED fixation light • Near-Infrared LED illumination and transillumination of the eyelid	• Visible White Class I LED illumination • Visible LED fixation light	• Visible and Infrared LED illumination • Red LED Fixation Light • White and Cobalt Blue Light
Illumination Exposure Parameters	Complies with ISO 15004-2:2007 Group 2 instrument for safety	Complies with ISO 15004-2:2007 Group 1 instrument for safety	Complies with ISO 15004-2:2007 Group 2 instrument for safety
Brightness Control	No brightness control adjustment by user	No brightness control adjustment by user	Unknown
Material Flammability	Materials near light source comply with UL 94V-1	Materials near light source comply with UL 94V-1	Unknown
Maximum Temperature of Held or Accessible Parts	Ambient temperature of parts of device held by operator or accessible to patient	Ambient temperature of parts of device held by operator or accessible to patient	Unknown

TABLE 5-1. PREDICATE DEVICE COMPARISON TABLE

Comparison Feature	LipiView II Interferometer	Predicate LipiView Interferometer (K091935 and K122481)	Optomed Smartscope M5 Digital Camera (K132186)
Data Collection and/or Display Systems	• Touchscreen display to view images • Stores images on computer and external media • Support for off-the-shelf USB printer and media that are compatible with Windows 7 and USB2.0	• Touchscreen display to view images • Stores images on computer and external media • Support for off-the-shelf USB printer and media compatible with Windows XP and USB1.0	• Active matrix color TFT LCD • Stores images on external media (flash memory card) • USB1.1 terminal compatible with Windows XP/Vista/7
Electrical Safety and Electromagnetic Compatibility	• AC-powered • Complies with ANSI 60601-1:2005 (3rd edition) and IEC 60601-1-2: 2007 (3rd edition)	• AC-powered • Complies with IEC 60601-1:1995 (2nd edition) and IEC 60601-1-2: 2001 (2nd edition)	• Rechargeable NiMH Battery with charging unit • Complies with IEC 60601-1:2005 (3rd edition) and IEC 60601-1-2: 2007 (3rd edition)
Chin/Forehead Rest Support	Integrated chin rest and forehead support is disinfected with alcohol prior to use and storage	Integrated chin rest and forehead support is disinfected with alcohol prior to use and storage	May be used with slit lamp adapter for chin rest support