December 10, 2018

TearScience, Inc.
Christy Coleman
Vice President, Clinical & Regulatory Affairs
5151 McCrimmon Pkwy.
Ste. 250
Morrisville, NC 27560

Re: K182506
Trade/Device Name: LipiScan Dynamic Meibomian Imager
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: September 11, 2018
Received: September 12, 2018

Dear Christy 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Bradley S. Cunningham -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182506

Device Name
LipiScan™ Dynamic Meibomian Imager

Indications for Use *(Describe)*

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.

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.

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510(k) SUMMARY

PREPARATION DATE:	November 6, 2018
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 & Regulatory Affairs
DEVICE TRADE NAME:	LipiScan™ Dynamic Meibomian Imager
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II; 21 CFR 886.1120
PRODUCT CODE:	HKI
PREDICATE DEVICE:	**Trade/Device Name:** LipiView® II Ocular Surface Interferometer (K152869) **Regulation Number:** 21 CFR 886.1120 **Regulation Name:** Ophthalmic Camera **Regulatory Class:** Class II **Product Code:** HKI, HJO

DEVICE DESCRIPTION:

The LipiScan™ Dynamic Meibomian Imager (DMI) (Model DMI-1000) is a bench-top ophthalmic camera used to image the meibomian glands. LipiScan™ contains a computer system, electronics, chin and forehead rest, camera and attached lens, illuminator, touchscreen display, handheld near-infrared (IR) lid everter and power supply. The chin and forehead rest and handheld near IR lid everter are the only components of the device that contact the patient's intact skin.

LipiScan™ uses near infrared (NIR) illumination and an NIR-sensitive high-resolution camera to image the meibomian glands. The tissue between the meibomian glands and the surface of the eyelid is transparent to NIR light; the glands reflect NIR wavelengths, allowing them to be imaged. The images of the glands may be viewed on the computer screen display and in a printed report.

LipiScan™ complies with Group 1 requirements of both ISO 15004-2:2007 (Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection) and ANSI Z80.36-2016 (Light Hazard Protection for Ophthalmic Instruments). Group 1 is for ophthalmic instruments for which no potential light hazard exists.

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

INDICATIONS FOR USE:

Indications for Use Statement: LipiScan™ Dynamic Meibomian Imager (DMI) 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.

LipiScan™ DMI has the same Indications for Use to image the Meibomian glands as the predicate LipiView® II Ocular Surface Interferometer (K152869). Note that the predicate device has additional indications (i.e., tear film imaging and thickness measurement, and ocular surface imaging under white light), which are not included in the subject LipiScan™ DMI.

TECHNOLOGICAL CHARACTERISTICS:

LipiScan™ has the same fundamental scientific technology as the predicate LipiView® II Ocular Surface Interferometer. As summarized below, most of the technological characteristics are the same between devices. A comparison of the technology between LipiScan™ and the predicate device is summarized below and in Table 1.

Similarities: The predicate LipiView® II device and LipiScan™ have the same principle of operation as an ophthalmic camera to image the meibomian glands using a LED light source in the near-infrared spectrum. Both bench-top devices have similar components including a computer system, electronics, chin and forehead rest, camera and lens, illuminator, touchscreen display, and handheld near IR lid everter. Both devices may be used with off-the-shelf (OTS) USB accessories, have connections for an external HDMI monitor, and operate wirelessly with networks.

Similar design features between LipiScan™ and the predicate device include: an adjustable chin and forehead rest; same patient contact materials and disinfection method; high definition digital camera; surface NIR illumination; and transillumination of the eyelid with the handheld near IR lid everter. Both devices comply with standards for light hazard protection. Both devices have an AC-power source in compliance with standards for electrical safety and electromagnetic compatibility (EMC). Both devices have flame retardant materials. Both devices have ambient temperature of parts of the device held by operator or accessible to the patient in compliance with standards.

The software on both devices runs on a Microsoft Windows-based operating system with a touchscreen display graphical user interface. Similar software features include: password-protected user login; patient database entry; real-time display to acquire and view images; touchscreen user controls for camera; storage of images on the computer; printed or saved reports; and export of images to USB external media or electronic medical record system via a wireless network.

Differences: The predicate LipiView® II Interferometer has design features that are not included in LipiScan™ such as: a white light Class I LED illuminator; visible LED fixation light; full color images and video; pushbutton controls; and software designed for tear film and ocular imaging and lipid layer thickness measurement using interferometry. These features are necessary to support the additional indications of the predicate device but are not needed for meibomian gland imaging. Therefore, these additional design features to support additional indications for use in the predicate device do not affect safety and effectiveness of the LipiScan™ for imaging the meibomian glands.

The devices also use different but equivalent methods to position the camera and focus the image. The predicate device uses electromechanical stages. Conversely, LipiScan™ uses a dual chinrest with a sensor, high-resolution camera capable of capturing the entire field of view, and an electronically controlled lens. Furthermore, unlike the predicate device, LipiScan™ is designed to be portable.

PERFORMANCE TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION:

Design verification and validation and usability testing demonstrate that LipiScan™ DMI is as safe and effective as the predicate device for the intended use to image the Meibomian glands using near-infrared light. Performance testing demonstrates that LipiScan™ DMI is substantially equivalent to the predicate device, and the design differences as compared to the predicate device do not raise new questions of safety and effectiveness.

Biocompatibility

The LipiScan™ DMI does not contact the patient's eye. LipiScan™ DMI directly contacts the patient's intact skin (surface-contacting device) for up to 15 minutes (limited (≤ 24 hours) contact duration). The surface-contacting material composition and device manufacturing process are the same as those of the predicate LipiView® II device cleared in K152869; therefore, new biocompatibility testing is not needed.

Sterilization, Cleaning and Disinfection

The LipiScan™ DMI is used non-sterile and sterilization is not applicable. Patient contact surfaces are disinfected with 70-90% isopropyl alcohol prior to each patient use and prior to storage. The verification testing shows that the device patient contact materials are compatible with isopropyl alcohol disinfection. Additionally, the *Instructions for Use* provide instructions for cleaning other surfaces of the device that the operator may contact during use but do not have direct patient contact.

Electrical Safety and Electromagnetic Compatibility (EMC)

To support substantial equivalence in electrical safety and electromagnetic compatibility (EMC) to the predicate device, LipiScan™ DMI was tested for conformance to the following standards:

- ANSI AAMI ES60601-1 2005 /(R)2012 and A1:2012: C1:2009/(R)2012 and A2:2010/(R) Consolidated Text Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD)
- IEC 60601-1-2 2007: Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

Light Hazard Protection

LipiScan™ DMI uses near-infrared (NIR) illumination and an NIR-sensitive high-resolution camera to image the meibomian glands and captures black and white still images. Whereas, the predicate device, LipiView® II, uses a white light Class I LED illuminator, visible LED fixation light and captures full color still images and video.

Both devices comply with standards for light hazard protection. LipiScan™ DMI meets Group 1 ophthalmic instrument requirements as defined in the ISO 15004-2: 2007 and ANSI Z80.36:2016 standards for which no potential light hazard exists. The predicate LipiView® II device meets Group 2 ophthalmic instrument requirements for which a potential light hazard exists.

Software

LipiScan™ DMI is based on the same fundamental technology as the predicate device, LipiView® II Ocular Surface Interferometer. The LipiScan™ DMI software development was largely based on the LipiView® II gland imaging software. As for the predicate device, LipiScan™ DMI software is categorized as a Minor Level of Concern. The software documentation for the LipiScan™ DMI is provided per *FDA Guidance for the Content of Pre-Market Submissions for Software Contained in Medical Devices* (May 11, 2005). Verification and Validation testing were completed to demonstrate that the device performance complies with specifications and requirements identified for the LipiScan™ DMI software.

CONCLUSIONS:

The LipiScan™ Dynamic Meibomian Imager has the same intended use, Indications for Use and fundamental scientific technology as the predicate device. Performance testing demonstrates that LipiScan™ is substantially equivalent in intended use and technological characteristics to the predicate device. Based on performance testing, LipiScan™ is at least as safe and effective as the predicate device.

TABLE 1. PREDICATE DEVICE COMPARISON TABLE

Comparison Feature	LipiScan™ Dynamic Meibomian Imager (DMI)	Predicate LipiView® II Ocular Surface Interferometer (K152869)	Comparison
Intended Use per 21 CFR 886.1120	Bench-top, AC-powered device intended to take photographs of the eye and the surrounding area	Bench-top, AC-powered device intended to take photographs of the eye and the surrounding area	Same intended use
Indications for Use	LipiScan™ Dynamic Meibomian Imager (DMI) 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.	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: • Meibomian glands under near-infrared (NIR) illumination. • Specular (interferometric) observations of the tear film. Using these images, LipiView® II measures the absolute thickness of the tear film lipid layer. • The ocular surface and eyelids under white illumination. All of these image types can be photographically documented and visually monitored.	Same Indications for Use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands. The predicate device has additional indications that are not included in LipiScan™. Therefore, this difference does not raise new questions of safety and effectiveness for LipiScan™ for its intended use.
Rx only/OTC	Prescription Device	Prescription Device	Same intended use
Operation Principle	Uses near infrared (NIR) illumination to image the meibomian glands	Uses near infrared (NIR) illumination to image the meibomian glands	Same principle of operation
Components	Computer system, electronics, adjustable chin and forehead rest, high definition digital camera, lens, illuminator, touchscreen display, and handheld near IR lid everter	Computer system, electronics, adjustable chin and forehead rest, high definition digital camera, lens, illuminator, touchscreen display, and handheld near IR lid everter	Same technologic characteristics
Accessory Support	• Support for OTS USB printer and media compatible with Windows 7 and USB2.0 • External HDMI monitor connection • Operates with wireless networks	• Support for OTS USB printer and media compatible with Windows 7 and USB2.0 • External HDMI monitor connection • Operates with wireless networks	Same technologic characteristics
Patient Contact Materials	Chin and forehead rests and lid everter are made of the same patient contact materials and use the same disinfection method	Chin and forehead rests and lid everter are made of the same patient contact materials and use the same disinfection method	Same technologic characteristics

TABLE 1. PREDICATE DEVICE COMPARISON TABLE

Comparison Feature	LipiScan™ Dynamic Meibomian Imager (DMI)	Predicate LipiView® II Ocular Surface Interferometer (K152869)	Comparison
Illumination Source	• NIR LED surface illumination and transillumination of the eyelid	• NIR LED surface illumination and transillumination of the eyelid • Visible White Class I LED illumination • Visible LED fixation light	Both devices use NIR illumination. Predicate device has additional light sources to support additional indications and functionality that are not in LipiScan™.
Illumination Exposure Parameters	Complies with ISO 15004-2:2007 and ANSI Z80.36:2016 Group 1 instrument	Complies with ISO 15004-2:2007 Group 2 instrument	Both devices comply with standards
Electrical Safety and EMC	Complies with ANSI AAMI ES60601-1:2005/ (R)2012 and A1:2012: C1:2009/ (R)2012 and A2:2010/(R) and IEC 60601-1-2:2007	Complies with ANSI ES 60601-1:2005 (Third Edition) and IEC 60601-1-2: 2007 (Third Edition)	Both devices comply with standards
Material Flammability	Materials near light source and device enclosure comply with UL 94:2013	Materials near light source comply with UL 94:2013	Both devices comply with standards
Temperature of Held or Accessible Parts	Ambient temperature of parts of device held by operator or accessible to patient compliant to ISO 15004-1:2006	Ambient temperature of parts of device held by operator or accessible to patient compliant to ISO 15004-1:2006	Both devices comply with standards
Software Features	• Microsoft Windows Operating System • Touchscreen display GUI • Password-protected user login, patient database entry, real-time display to acquire and view images, image storage and export to external media, printed or saved reports • Touchscreen user controls • Black and white still images • Software module for gland imaging	• Microsoft Windows Operating System • Touchscreen display GUI • Password-protected user login, patient database entry, real-time display to acquire and view images, image storage and export to external media, printed or saved reports • Touchscreen and pushbutton user controls • Full color still images and video • Software modules for tear film and thickness measurement, ocular imaging and gland imaging	Same technologic characteristics, except the predicate device also has pushbutton controls, full color images and video, and software designed for tear film and ocular imaging and lipid layer thickness measurement. These additional features are needed to support additional indications for the predicate device but are not needed for meibomian gland imaging.
Camera Alignment and Image Focus Methods	Dual chinrest with sensor and camera capable of capturing entire field of view to align camera to the patient's eye and electronically controlled lens to focus the image	Electromechanical stages to align camera to patient's eye and focus the image	Methods are equivalent. Motorized stages are not needed to capture and focus an image using LipiScan™, as shown by performance testing.