April 27, 2026

Sight Sciences, Inc.
Rachel Franco
Lead Regulatory Affairs Specialist
4040 Campbell Ave.
Suite 100
Menlo Park, CA 94025

Re: K252409
Trade/Device Name: TearCare MGX System
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ
Dated: March 20, 2026
Received: March 23, 2026

Dear Ms. Franco:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252409

Device Name
TearCare MGX System

Indications for Use *(Describe)*

The Sight Sciences TearCare MGX™ System is a thermal-activated gland expression therapy that improves meibomian gland function in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression 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.

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510(k) SUMMARY

Submitter Information

510(k) Owner: Sight Sciences, Inc.
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Tel: 408-221-7376

Date Prepared: April 21, 2026

Device Name and Classification

TRADE NAME:	TearCare MGX System
COMMON NAME:	N/A
CLASSIFICATION NAME:	Eyelid Thermal Pulsation System
REGULATION NUMBER:	21 CFR 886.5200
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE:	ORZ

Predicate Device

Device Name: TearCare MGX System
510(k) Holder: Sight Sciences, Inc.
510(k) Number: K242786
Clearance Date: April 15, 2025

Indications for Use

The Sight Sciences TearCare MGX™ System is a thermal-activated gland expression therapy that improves meibomian gland function in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands.

Device Description

The TearCare MGX System is designed to deliver controlled, precise heat to the tarsal plates and underlying meibomian glands of the eyelids for 15 minutes, followed by an optional warming hold time of up to 10 minutes to allow for manual expression. Optionally, eyelid debridement may be performed prior to the thermal therapy as well. The TearCare MGX System is comprised of a re-usable SmartHub, SmartCable, Charging Nest and charging adapter, and single use SmartLids. The subject TearCare MGX System is comprised of the components described in **Table 1** below.

Table 1 TearCare MGX System components

Catalog Number	Description
5-118	TearCare MGX System Technology Kit, which includes:
	TearCare MGX SmartHub (Cat no. 5-113)
	SmartCable (Cat no. 5-115)
	Charging Nest and charging adapter (Cat no. 5-114)
5-109	One (1) packaged pair of non-sterile, single-use TearCare MGX SmartLids (each pair includes one left and one right SmartLid)

The TearCare MGX System is operated by an eye care practitioner (ECP), who affixes the SmartLids to the patient's eyelids, connects the SmartLids to the SmartHub with the SmartCable, and initiates the therapy session on the SmartHub. In the same manner as the predicate device, the system increases the temperature from the lowest warmth setting (41°C) to the highest warmth setting (45°C) when the therapy starts. The SmartHub controls the temperature until the 15-minutes of therapy are complete, at which time the system visually and audibly signals the end of therapy. At the end of the 15-minute core therapy, the TearCare MGX System can be transitioned to an optional Warming Hold Time (WHT) for up to a maximum of 10 minutes. WHT holds the temperature at the lowest warmth setting (Warmth setting 1 and temperature set point of 41°C) allowing the ECP to individually express each eyelid while the lids are warm. To complete the TearCare MGX procedure, the ECP removes the SmartLid devices one at a time from the patient, then uses the separately available meibomian gland expression forceps (Clearance Assistant) to manually express the meibomian glands immediately following the eyelid heat therapy. Heat is discontinued once the SmartLid is removed prior to expression, at the end of the optional 10-minute WHT, or at any time the eye care practitioner utilizes the SmartHub control to interrupt (pause or stop) treatment.

The subject TearCare MGX System is technologically the same as the predicate TearCare MGX System cleared under 510(k) K242786. Notably, there are no changes to the system impacting thermal exposure and limits regarding temperature control and regulation. The subject device of this submission proposes changes to the TearCare MGX System that impact the Instructions for Use (IFU) with updates to the indication for use and an added optional step for eyelid debridement prior to therapy, rather than a device technological change. The procedural instructions for use are updated with instruction for optional debridement and the use of associated Clearance Assistant Plus device. A comparison of the technological characteristics between the subject TearCare MGX System compared with the predicate TearCare MGX System device is shown in **Table 2** below.

Table 2 Comparison of Technological Characteristics with the Predicate Device

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K242786 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
Device Classification	Class II	Class II	**Equivalent**
Classification Product Code	ORZ	ORZ	**Equivalent**
Regulation Number	886.5200	886.5200	**Equivalent**
Intended Use	The TearCare MGX System is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is intended for use in adult patients with meibomian gland dysfunction, also known as evaporative dry eye disease.	The TearCare MGX System is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is intended for use in adult patients with meibomian gland dysfunction, also known as evaporative dry eye disease.	**Equivalent**
Indications For Use	The Sight Sciences TearCare MGX™ System is a thermal-activated gland expression therapy that improves meibomian gland function in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands.	The TearCare MGX™ System is intended for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands.	**Equivalent** The subject device indications for use maintains the same intended use as the predicate device and utilizes directed descriptive language to rephrase the therapy while adding clinical performance description supported by already referenced OLYMPIA clinical study data. The changes do not raise different questions of safety and effectiveness.
Technological Characteristics			
Device Description	• Disposable SmartLid components are attached to the external surface of the eyelids and connect to a reusable SmartHub controller which generates the heat that is delivered to the eyelids	• Disposable SmartLid components are attached to the external surface of the eyelids and connect to a reusable SmartHub controller which generates the heat that is delivered to the eyelids	**Equivalent** The Clearance Assistant Plus device is of the same material and construction as the Clearance Assistant device, except for the debridement edge. Use of the Clearance Assistant Plus device

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K242786 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
	• A separate, sterile disposable Clearance Assistant™ is used in conjunction with the TearCare MGX System to perform manual expression of the meibomian glands immediately following heat treatment with TearCare • A separate, sterile disposable tool Clearance Assistant Plus™ is identified as an optional alternative tool which may be used for eyelid debridement and manual gland expression.	• A separate, sterile disposable Clearance Assistant™ is used in conjunction with the TearCare MGX System to perform manual expression of the meibomian glands immediately following heat treatment with TearCare	and eyelid debridement and meibomian gland expression has been evaluated and is supported by clinical study data.
Sterilization	The TearCare MGX SmartHub, SmartCable, Charging Nest and SmartLids are non-sterile	The TearCare MGX SmartHub, SmartCable, Charging Nest and SmartLids are non-sterile	**Equivalent**
Single Use or Reusable	• SmartLids: single use • SmartHub, SmartCable, and Charging Nest: reusable	• SmartLids: single use • SmartHub, SmartCable, and Charging Nest: reusable	**Equivalent**
Operation Control	Eye Care Practitioner	Eye Care Practitioner	**Equivalent**
Mechanism for Heat Generation	Polymer encapsulated resistive heating element	Polymer encapsulated resistive heating element	**Equivalent**
Power source	Batteries, DC power	Batteries, DC power	**Equivalent**
Point of Use	In-Office	In-Office	**Equivalent**
Pre-Therapy Debridement	Yes - An optional procedural step of eyelid debridement is available to perform prior to thermal therapy.	No	Performance of eyelid debridement prior to thermal therapy is optional. Debridement has been evaluated in a clinical study demonstrating that the added optional step does not impact device safety and effectiveness.
Treatment protocol	15 minutes of heat treatment with the TearCare MGX System, followed manual	15 minutes of heat treatment with the TearCare MGX System, followed manual	**Equivalent**

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K242786 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
	expression of all four eyelids using the Clearance Assistant which typically requires 5-10 minutes. An optional warming hold time is available following heat treatment to allow flexibility to perform expression while the eyelids are warm.	expression of all four eyelids using the Clearance Assistant which typically requires 5-10 minutes. An optional warming hold time is available following heat treatment to allow flexibility to perform expression while the eyelids are warm.	
Temperature regulation	Temperature at the SmartLids are continuously monitored by the SmartHub to ensure it does not exceed the maximum allowable temperature	Temperature at the SmartLids are continuously monitored by the SmartHub to ensure it does not exceed the maximum allowable temperature	**Equivalent**
Therapeutic Temperature Range	Automatic ramp from 41 to 45°C in five 1°C steps. User can adjust to any of these 5 temperature settings	Automatic ramp from 41 to 45°C in five 1°C steps. User can adjust to any of these 5 temperature settings	**Equivalent**
Temperature Accuracy	± 0.7°C	± 0.7°C	**Equivalent**
Maximum Sustainable Therapeutic Temperature (i.e., for the duration of the procedure)	46.74°C	46.74°C	**Equivalent**
Maximum Absolute Temperature Limit (at any exposure time)	47°C	47°C	**Equivalent**
Maximum Outer Eyelid Surface Temperature Limit (Safety Limit)	46.99°C for 2 seconds prior to automatic temperature downregulation	46.99°C for 2 seconds prior to automatic temperature downregulation	**Equivalent**
Rate of Heating (time to reach target temperature)	< 60 seconds to initial target level 1, then additional 30 seconds to reach each additional level (total of 5 temperature levels)	< 60 seconds to initial target level 1, then additional 30 seconds to reach each additional level (total of 5 temperature levels)	**Equivalent**

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K242786 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
Pressure Control	Manual: Eye Care Practitioner, using separately provided expressor forceps determines pressure (based on patient feedback and direct viewing of glands)	Manual: Eye Care Practitioner, using separately provided expressor forceps determines pressure (based on patient feedback and direct viewing of glands)	**Equivalent**
Pressure Type	Manual expression using separately provided Clearance Assistant expression forceps	Manual expression using separately provided Clearance Assistant expression forceps	**Equivalent**
Treatment of upper and lower eyelids	Concurrent for upper and lower eyelids of both right and left eye	Concurrent for upper and lower eyelids of both right and left eye	**Equivalent**
Packaging (pertinent to disposable)	PETG tray within a carton	PETG tray within a carton	**Equivalent**
Performance Testing			
Biocompatible patient-contacting materials (ISO 10993-1)	Limited contact duration device per 10993-1 Yes, medical-grade silicone/acrylic tape, Polyolefin Foam, polyimide, Santoprene, and makrolon polycarbonate supported by cytotoxicity testing per ISO 10993-5, primary skin irritation per ISO 10993-23, and repeated patch dermal sensitization testing per ISO 10993-10. Primary skin irritation, intracutaneous irritation, guinea pig maximization, and ocular irritation testing per ISO 10993-10 for medical-grade silicone/acrylic tape, Polyolefin Foam and polyimide. Santoprene and makrolon polycarbonate supported by cytotoxicity testing per ISO 10993-5, primary skin irritation per ISO	Limited contact duration device per 10993-1 Yes, medical-grade silicone/acrylic tape, Polyolefin Foam, polyimide, Santoprene, and makrolon polycarbonate supported by cytotoxicity testing per ISO 10993-5, primary skin irritation per ISO 10993-23, and repeated patch dermal sensitization testing per ISO 10993-10. Primary skin irritation, intracutaneous irritation, guinea pig maximization, and ocular irritation testing per ISO 10993-10 for medical-grade silicone/acrylic tape, Polyolefin Foam and polyimide. Santoprene and makrolon polycarbonate supported by cytotoxicity testing per ISO 10993-5, primary skin irritation per ISO	**Equivalent**

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K242786 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
	10993-23, and guinea pig maximization testing per ISO 10993-10.	10993-23, and guinea pig maximization testing per ISO 10993-10.	
Shelf Life	25-month shelf life for the SmartLids	25-month shelf life for the SmartLids	**Equivalent**
Thermal Safety	• TearCare System bench testing verified function of thermal safety requirements	• TearCare System bench testing verified function of thermal safety requirements • Clinical testing measured the corneal, inner and outer eyelid temperatures to validate thermal safety requirements	**Equivalent** Subject device does not change parameters of thermal performance of the device, therefore clinical testing of predicate device is applicable to the subject device
Software	Testing was performed to verify/validate that the system software met all requirements	Testing was performed to verify/validate that the system software met all requirements	**Equivalent**
Electrical Safety per IEC 60601-1	Meets requirements	Meets requirements	**Equivalent**
Electromagnetic Compatibility (EMC) per IEC 60601-1-2	Meets requirements	Meets requirements	**Equivalent**

Risk Analysis

The risk management process at Sight Sciences complies with ISO 14971:2019 *"Medical devices -- Application of risk management to medical devices."* As required by this standard, risk analyses are conducted according to defined procedures, using experienced, qualified personnel from multiple functions throughout the organization with prior experience in risk assessment. All the identified hazards were mitigated to an acceptable level of risk. The potential benefits to patients outweigh the low residual risk, taking into consideration the indications for use of the TearCare MGX System.

Summary of Testing Performed

Clinical Study Summary

OLYMPIA Study

The "OLYMPIA" study was a prospective, multicenter, randomized, non-inferiority, masked, controlled clinical trial. The OLYMPIA study has been described in previous TearCare 510(k) submission K213045. The primary effectiveness endpoints for OLYMPIA included the mean change from baseline to 1-month in Tear Break-Up Time (TBUT) and Total Meibomian Gland Secretion Score (MGSS). Secondary effectiveness endpoints included the mean change from baseline to 1-month in Ocular Surface Disease Index (OSDI) score, corneal and conjunctival staining scores, Symptom Assessment in Dry Eye (SANDE) scores, Eye Dryness Score and meibomian gland health as assessed with meibomian glands yielding any liquid (MGYAL) and meibomian glands yielding clear liquid (MGYCL). Patients enrolled in the OLYMPIA study had Ocular Surface Disease Index (OSDI) baseline scores of 23-79 (Note - a lower score is better), and the mean baseline score was 52.0 ± 14.4). Baseline (pre-TearCare treatment) MGSS was 6.5 (95% CI 6.01, 7.07) which improved at 1 month following TearCare treatment to 17.7 (95% CI 15.75, 19.73), an improvement of 11.2 (95% CI 9.3, 13.1) or 1.7-fold. There was also improvement in TBUT. At pre-treatment baseline TBUT was 4.6 seconds (95% CI 4.41, 4.82) which improved to 7.6 seconds (95% CI 6.84, 8.43) at one month post treatment. These improvements in ocular signs of dry eye resulted in symptom improvement as measured by the OSDI; the mean OSDI decreased from 52.0 at pre-treatment baseline to 24.2 at 1 month post-treatment, a change of -27.9. OLYMPIA shows treatment with the TearCare system provides clinically meaningful improvement in meibomian gland function in terms of both number of glands actively secreting meibum (MGSS, MGYAL) and overall meibum quality (MGSS, MGYCL). The effect of improvement in gland function can readily be seen in decreased rate of tear film evaporation (improved TBUT) and ultimately in improved patient symptoms (OSDI).

While effectiveness can be typically achieved following a single treatment, it is recommended to monitor patients for recurrence of signs or symptoms that would indicate a retreatment may be warranted.

SAHARA Study

The "SAHARA" study was a prospective, randomized, assessor-masked, multicenter, controlled, superiority trial that assessed the TearCare procedure compared to a leading pharmaceutical drop (cyclosporine ophthalmic emulsion, CsA). While SAHARA[1] evaluated the safety and effectiveness of the TearCare System in patients with dry eye disease compared to CsA, only the TearCare arm is presented in support of TearCare device safety and effectiveness. In addition to the standard TearCare therapy, the SAHARA study included debridement of all four eyelid margins prior to the therapy and if desired,

[1] Ayres B, et al. A randomized, controlled trial comparing Tearcare and cyclosporine ophthalmic emulsion for the treatment of dry eye disease (SAHARA). Clin Ophthalmol 2023;17:3925-3940

immediately following thermal therapy. The SAHARA study evaluated the TearCare System device, not the TearCare MGX System, though the core therapy parameters are the same between the two devices.

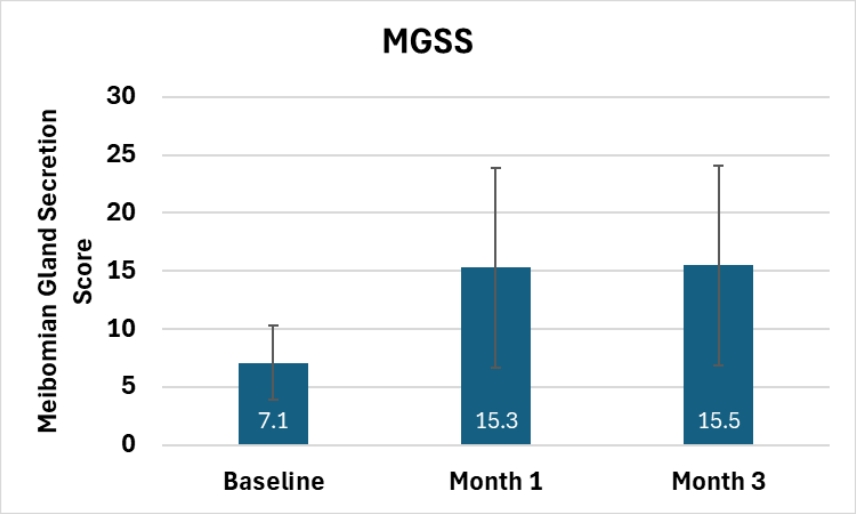
The measures to assess and evaluate the improvement of gland expression include measures of tear break-up time (TBUT), ocular surface disease index (OSDI), meibomian gland secretion score (MGSS), and meibomian glands yielding any liquid (MGYAL) S. These measures of meibomian gland health have been assessed in the OLYMPIA clinical study as well as in the SAHARA study. With the evaluation of these effectiveness endpoints, the TearCare System has shown that the thermal treatment and manual expression improvess meibomian gland function (meibomian gland secretion and quality of tear film).

A total of 172 subjects from 19 investigative centers in the United States participated in the TearCare arm of the SAHARA study, comprised of 120 female and 52 males, ages 22 to 88 years (mean = 55.5 ± 14.8 years). The primary effectiveness endpoints included mean change from baseline in Tear Break-Up Time (TBUT) and mean change from baseline in OSDI score. Secondary effectiveness endpoints included the mean change in total Meibomian Gland Secretion Score, cornea and conjunctival staining scores, SANDE scores, Eye Dryness Score and meibomian gland health as assessed by number of meibomian glands yielding any liquid, and number of meibomian glands yielding clear liquid. **Table 3** shows the outcomes for TBUT and OSDI at Month 1. An increase in TBUT and a decrease in OSDI represent improvements.

Table 3 Main Effectiveness Outcomes at Month 1

Outcome	SAHARA	
	Baseline	Month 1
TBUT (seconds)	4.4	6.3
OSDI	50.4	35.4

Figure 1 below shows Mean MGSS at SAHARA Study Baseline and at one and three months after the TearCare treatment. MGSS more than doubled at each time point representing mean (SD) change from baseline of 8.1 (8.3) and 8.3 (8.3), respectively.



Error bars are + or – one standard deviation. Month 1 and Month 3 versus Study Baseline.

Figure 1. Meibomian Gland Secretion Score. Mean MGSS at SAHARA Study Baseline, Month 1, and Month 3

Scatterplots are used to show eye level change in MGSS in **Figure 2** below. Points above diagonal represent improved MGSS; on diagonal, no change; below diagonal, worsening. A, Month 1, n= 338, B, Month 3, n=340

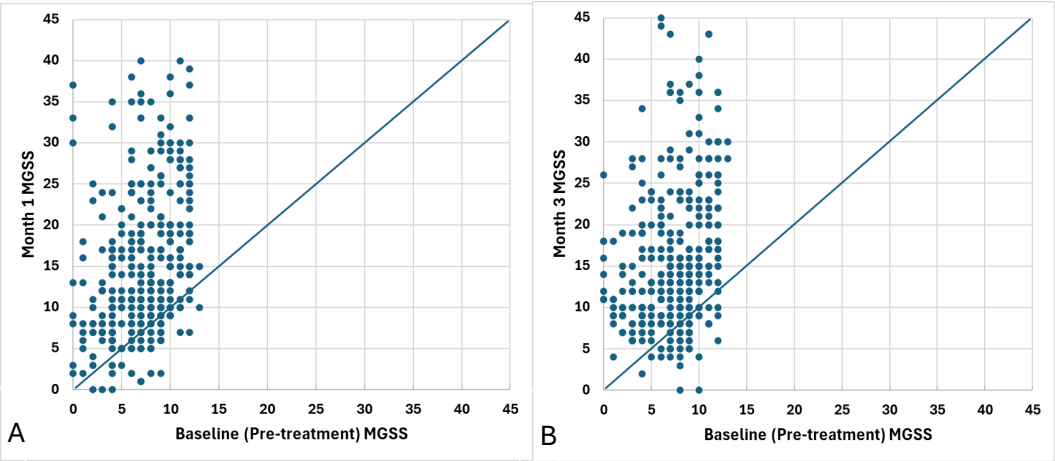


Figure 2. Scatterplot: Baseline MGSS (x-axis) vs. Post-treatment MGSS (y-axis)

At Month 1, 283 of 338 eyes (84%) had improved MGSS, 17 of 338 (5%) had no change, and 38 of 338 (11%) had worse MGSS. At Month 3, 293 of 340 (86%) improved, 9 of 340 (3%) had no change, and 38 of 340 (11%) worsened.

The measure of meibomian glands yielding any liquid (MGYAL) is an actual count of the number of meibum secreting glands secreting meibum regardless of meibum quality. In SAHARA, the number of secreting glands from the 5 central glands in the lateral, central, and temporal thirds of the lower eyelids was assessed therefore the score for each eye could be between zero and 15. One month after the TearCare treatment at Study Baseline the average MGYAL was increased from 5.9 to 9.5. This increase in functional glands was maintained through Month 3 where average MGYAL was 9.9.

Optional Debridement

The primary safety endpoint was procedure related adverse events (AE). The secondary safety endpoints included change in best corrected visual acuity (BCVA) and change in intraocular pressure (IOP). Any adverse events that could reasonably be a consequence of eyelid debridement would likely have been observed at the time of debridement or shortly thereafter. There were only three AE for 172 subjects (1.7%) involving the eyelid in the SAHARA trial during the first 30 days post-treatment, all at a frequency of ~1% or less which was similar to the incidence of lid-related AE in two prior studies (CHEETAH[2] and OLYMPIA) which did not include lid debridement prior to TearCare. **Table 3** lists the frequency and percentage of all ocular adverse events for SAHARA broken down into those occurring within 30 days of treatment, and those occurring after 30 days. Any AE that could reasonably be a consequence of eyelid debridement would likely have been observed at the time of debridement or shortly thereafter.

[2] Karpecki P, Wirta D, Osmanovic S, Dhamdhere K. A prospective, post-market, multicenter trial (CHEETAH) suggested TearCare system as a safe and effective blink-assisted device for the treatment of dry eye disease. Clin Ophthalmol 2020;14:4551-4559; Gupta PK, Holland EJ, Hovanesian J, et al. TearCare for the treatment of meibomian gland dysfunction in adult patients with dry eye disease: a masked randomized controlled trial. Cornea 2022;417-426

Table 4 Ocular Adverse Events

Adverse Event	SAHARA AE 1st 30 days post-treatment (debridement) n (% per 172 subjects)	SAHARA AE Day 31 to Month 6 post-treatment (debridement) n (% per 172 subjects)
AE with eyelid involvement		
Chalazion	-	2 (1.2)
Blepharitis	-	-
Eyelid irritation	1 (0.6)	-
Infection eyelid or ocular surface	-	1 (0.6)
Preseptal cellulitis	-	1 (0.6)
Stye	1 (0.6)	-
Swelling of the eyelid	1 (0.6)	-
Other Ocular AE		
BCVA loss of ≥ 2 lines Snellen	1 (0.6)	3 (1.7)
Blurred vision	-	1 (0.6)
Superficial punctate keratitis	-	-
Foreign body sensation (cornea)		1 (0.6)
Corneal erosion	-	1 (0.6)
Conjunctival injection (hyperemia)	1 (0.6)	-
Allergic conjunctivitis	-	1 (0.6)
Subconjunctival Hemorrhage	-	1 (0.6)
Iritis	-	-
Posterior vitreous detachment	1 (0.6)	-
Vitreomacular Traction	-	1 (0.6)
Worsening of Dry Eye	-	1 (0.6)

In the SAHARA study debridement was required for all four eyelid margins prior to the TearCare thermal treatment . While there was no obvious addition to treatment effectiveness due to debridement (when outcomes are compared to the previous OLYMPIA study which did not include debridement), effectiveness remained statistically significant and clinically meaningful as was seen in the prior studies of TearCare without debridement. Only three eyelid related AE were observed in SAHARA within 30 days of TearCare treatment, all at a frequency of ~1% or less which was similar to the incidence of lid-related AE in two prior studies (CHEETAH and OLYMPIA) which did not include lid debridement prior to TearCare. These outcomes support inclusion of eyelid debridement as a safe, optional procedure that can be performed at the time of TearCare treatment. Improvement in meibomian gland functionality as assessed by MGSS has been demonstrated in the SAHARA clinical study with an over two-fold greater mean MGSS (15.5 versus 7.1) at Month 3 compared to Study Baseline (**Figure 1**) and most subject eyes showing improvement in MGSS at Month 3 compared to Study Baseline (293 of 340, 86%) (**Figure 2**). Treatment with the TearCare system provides clinically meaningful improvement in meibomian gland function by enabling non-producing glands to begin producing liquid for most subjects with MGD associated dry eye disease.

Conclusions Drawn from Testing

The clinical evaluation of the OLYMPIA clinical trial, supported by SAHARA data, demonstrates that the TearCare MGX System is substantially equivalent to predicate TearCare MGX System with no impact to device safety and effectiveness with the updated indications for use and inclusion of optional eyelid debridement.