April 15, 2025

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

Re: K242786
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 14, 2025
Received: March 17, 2025

Dear Rachel 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242786

Device Name

TearCare MGX System

Indications for Use *(Describe)*

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.

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) Number: K242786

510(k) Owner: Sight Sciences, Inc.
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Tel: (877) 266-1144

Contact Person: Rachel M. Franco
Principal Regulatory Affairs Specialist
4040 Campbell Ave., Suite 100
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Tel: 408-221-7376

Date Prepared: April 9, 2025

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: K231084
Clearance Date: December 27, 2023

Indications for Use

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.

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. 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. 5-112)
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, 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 transitions to an optional Warming Hold Time (WHT) that may last 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 eye care practitioner to individually express each eyelid while the lids are warm. To complete the TearCare MGX procedure, the eye care practitioner 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) K231084. 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), rather than a device technological change. The procedural instructions for use are updated with additional instruction for the application of the SmartLids including an earpiece fitment check to assess whether the ear loop requires further support. A comparison of the technological characteristics between the subject TearCare MGX System compared with the predicate TearCare 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.) K231084 *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**
Indications For Use	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.	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**
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 • 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	• 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 • 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	**Equivalent**
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	• SmartLids: single use	**Equivalent**

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K231084 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
	• SmartHub, SmartCable, and Charging Nest: reusable	• SmartHub, SmartCable, and Charging Nest: reusable	
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**
Duration of Treatment	15 minutes of heat treatment with the TearCare MGX System, followed manual 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.	15 minutes of heat treatment with the TearCare MGX System, followed manual 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.	**Equivalent**
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**

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K231084 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
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**
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,	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,	**Equivalent**

Characteristic	TearCare MGX System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K231084 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
	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 10993-23, and guinea pig maximization testing per ISO 10993-10.	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 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

Electromagnetic Compatibility

Testing was performed to demonstrate that the System meets the electromagnetic requirements specified in IEC 60601-1-2.

Clinical Validation Study Summary

Clinical validation study was performed to validate the fit and retention of the TearCare MGX System earloop using modified Instructions for Use. In this clinical validation study, the TearCare MGX System was applied to 21 subjects. The study evaluated updated instructions for use regarding additional steps to "check for earpiece fitment," in order to assess whether the ear loops are properly installed and ensure that they can remain stable without the need for additional support. If a patient is identified through the earpiece fitment check to have "loose" fitment, then the eye care practitioner may proceed to use surgical tape to secure the earpiece. All earloop components remained affixed to the ears in all subjects for the duration of the 25 minute simulated treatment. The results of this clinical validation study demonstrate that the TearCare MGX device components remain securely affixed to the eyelid and head throughout a simulated 25 minute treatment when the SmartLids are applied according to updated instructions for use.

Conclusions Drawn from Testing

The results of the clinical evaluation demonstrates that the TearCare MGX System is substantially equivalent to the predicate TearCare MGX System.