August 18, 2026

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

Re: K262479
Trade/Device Name: TearCare System
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ
Dated: July 17, 2026
Received: July 20, 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
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262469

Please provide the device trade name(s).

TearCare System

Please provide your Indications for Use below.

The SightSciences TearCare® 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) SUMMARY

Submitter Information

510(k) Number: K262479

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

Contact Person: Rachel M. Franco
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Tel: 408-221-7376

Date Prepared: July 17, 2026

Device Name and Classification

TRADE NAME:	TearCare 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: K252409
Clearance Date: April 27, 2026

Indications for Use

The Sight Sciences TearCare® 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 System is designed to deliver controlled, precise heat to the tarsal plates and underlying meibomian glands of the eyelids for 15 minutes. After thermal treatment, the eye care professional uses a separately available TearCare Clearance Assistant instrument to express the meibomian glands. Optionally, eyelid debridement may be performed prior to thermal therapy as well. The TearCare System is comprised of a re-usable SmartHub, Charging Nest, and charging adapter, and single use SmartLids. The subject TearCare System is comprised of the components described in **Table 1** below.

Table 1 TearCare System components

Catalog Number	**Description**
5-116	TearCare SmartHub Kit, which includes:
	TearCare SmartHub (Cat no. 5-101)
	Charging Adapter (XP Power P/N VEP15US09)
	Charging Nest (Cat no- 5-102)
5-117	One (1) packaged pair of non-sterile, single-use TearCare SmartLids (each pair includes one left and one right SmartLid)

The subject TearCare System is technologically the same as the predicate TearCare MGX System cleared under 510(k) K252409. The subject device of this submission proposes to harmonize the labeling of the predicate device. Predicate K252409 updated labeling Instructions for Use (IFU) with updates to the indication for use and an added optional step for eyelid debridement prior to therapy. Additionally the instructions for use are updated to reference associated Clearance Assistant Plus device to perform debridement. A comparison of the technological characteristics between the subject TearCare 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 System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K252409 *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 Sight Sciences TearCare 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 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.	**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 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.	• 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 • 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.	**Equivalent**
Sterilization	Device components are non-sterile	Device components are non-sterile	**Equivalent**

Characteristic	TearCare System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K252409 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
Single Use or Reusable	• SmartLids: single use • SmartHub 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.	Yes - An optional procedural step of eyelid debridement is available to perform prior to thermal therapy.	**Equivalent**
Treatment Protocol	15 minutes of heat treatment with the TearCare System, followed manual expression of all four eyelids using the Clearance Assistant which typically requires 5-10 minutes.	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** Heat treatment therapy is equivalent. Optional warming hold time provides minimal contribution (reference K231084).
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	46.74°C	46.74°C	**Equivalent**

Characteristic	TearCare System (Sight Sciences, Inc.) *Subject Device*	TearCare MGX System (Sight Sciences, Inc.) K252409 *Predicate Device*	Comparison between TearCare System Subject and Predicate Device
(i.e., for the duration of the procedure)			
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**

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 System.

Clinical Study Summary

Clearance of predicate TearCare MGX System (K252409) was supported by OLYMPIA and SAHARA clinical studies. Both the OLYMPIA and SAHARA studies were conducted with the TearCare System as cleared under K213045. Given that the TearCare MGX System clearance was supported by clinical data generated with the TearCare System and that the two devices have the same technological characteristics, harmonization of the K252409 labeling with that of the subject TearCare System is justified.

Conclusions Drawn from Testing

The proposed changes to the TearCare System are limited to labeling harmonization with the legally marketed predicate TearCare MGX System (K252409) and do not involve any modifications to the device's technology, design, materials, or operating principles. The updated indications for use and inclusion of an optional debridement procedure step are supported by the same clinical evidence that supported clearance of the predicate device, the OLYMPIA and SAHARA studies, which were conducted using the TearCare System technology. Because the subject and predicate devices share identical technological characteristics and no new or significantly modified risks have been identified, the proposed labeling updates do not raise new questions of safety or effectiveness. Furthermore, existing verification and validation activities demonstrate that the device remains in its validated state, and no additional non-clinical or clinical testing is required to support this submission. Therefore, the data provided demonstrate that the TearCare System remains substantially equivalent to the predicate device with respect to safety, effectiveness, and intended clinical performance and it is appropriate to harmonize device labeling.