December 27, 2023

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

Re: K231084
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: November 20, 2023
Received: November 21, 2023

Dear Rachel M. 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231084

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: K231084

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

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

Date Prepared: December 11, 2023

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® System
510(k) Holder: Sight Sciences, Inc.
510(k) Number: K213045
Clearance Date: December 21, 2021

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 a powered device intended for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD).

The TearCare MGX™ System is comprised of a TearCare SmartLids® device (PN 07064) and a TearCare System Kit (PN 06985), containing the TearCare SmartHub™ (PN 07066), SmartCable (PN 06998), Charging Nest (PN 07067), and IFU (PN 06988). The TearCare MGX™ System warms the eyelid(s) by heating the SmartLids to a maximum set point of 45°C. Heat is applied to the external or cutaneous surface of the eyelids via the adherent, disposable SmartLids that are powered by the SmartHub. The TearCare MGX™ System can warm the eyelids of one or both eyes at a time. A medical grade silicone adhesive on the SmartLid device surface physically and thermally couples the devices to the external (cutaneous) surface of the eyelids. The SmartHub includes a device port for SmartLid device attachment via a SmartCable. Additionally, the SmartHub includes an intuitive touchscreen interface, temperature control processor, and a rechargeable battery. The operator affixes the devices to the patient's eyelids to initiate a treatment session and may adjust the system warmth level during a session. After completion of the core thermal cycle, an extended warming time will automatically begin and stay active for up to 10 minutes at a set target temperature of 41°C that is not permitted to not exceed 43°C. The SmartLid devices are disposable and are not intended to contact the cornea or conjunctival surfaces of the eye. The system automatically and gradually increases the temperature over 2-3 minutes until it reaches the target range of 41-45°C to melt the meibum blocking the meibomian glands. The core thermal cycle lasts 15 minutes, followed by an optional extended warming time which may last up to an additional 10 minutes.

After TearCare MGX treatment the eye care professional then uses a separately available Clearance Assistant™ to express the meibomian glands manually immediately following the eyelid heat treatment. The separately packaged sterile, single-use Clearance Assistant instrument is available from Sight Sciences and used in conjunction with the TearCare product. The Clearance Assistant instrument is a Class I, 510(k) exempt, meibomian gland expressor (Classification Product Code HNS, Regulation Number 886.4350). Safety and effectiveness of the TearCare MGX System has not been established when used in conjunction with any other meibomian gland expressor. Effectiveness of the TearCare MGX System has not been established without manual meibomian gland expression.
The TearCare MGX™ System consists of the following components:

- TearCare System Kit (P/N 06985) (includes):
  - TearCare SmartHub (P/N 07066)
    - IFU (P/N 06988)
  - SmartCable (P/N 06998)
  - Charging Nest (P/N 07067)
- TearCare SmartLids (P/N 07064)

SmartHub

The SmartHub is a battery-powered component that powers the SmartLids device assembly(s). It features a circuit board, microprocessor, a port for receiving the SmartCable, and a multi-pin contact for connecting to the Charging Nest. The SmartHub features a rechargeable Li-ion battery that when fully charged supplies power for at least 4 therapies when using two SmartLids® device assemblies. The SmartHub may be used with one or two SmartLids device assemblies connected. The SmartLids device assemblies are connected to the SmartHub through the SmartCable. The SmartHub is charged via a multi-pin charging port when not in use and when placed into the TearCare MGX™ System SmartHub Charging Nest. The SmartHub consists of a physical push button for power and a capacitive touchscreen with graphic user interface (GUI). Various types of soft button inputs and controls are utilized throughout the GUI to control display, system status information, therapy information, configuration parameters, and error information.

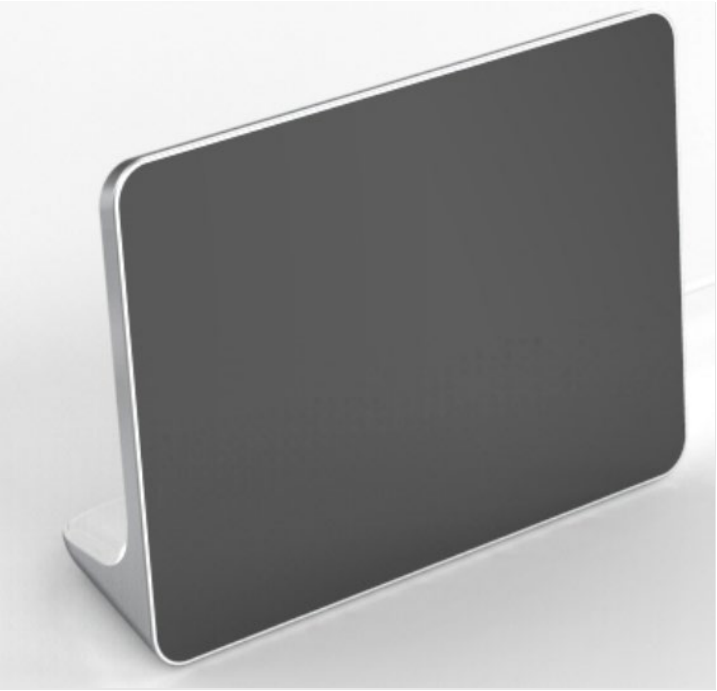

Figure 1, SmartHub

SmartLids®

The SmartLids® are flexible, software and sensor-controlled, single-use heat treatment components. The device assembly consists of a right and left configuration comprised of an earloop and two flexible laminated heating elements. The flexible heating element components adhere to the user's eyelid to provide heat during the therapy. The SmartHub regulates the power to the SmartLid® devices through connection with the SmartCable to provide the targeted temperature to the eyelids.

The SmartLid devices warm to a temperature set point of 41°- 45°C when affixed to the eyelids and powered by the SmartHub. A thin medical grade adhesive holds the SmartLids on the user's eyelids and positioning is stabilized by placement of the earloops.

SmartCable

The SmartCable is a reusable cable that connects the SmartLids to the SmartHub. The reusable SmartCable magnetically connects to the SmartLids earloops to provide the connection from the SmartLids to the SmartHub.

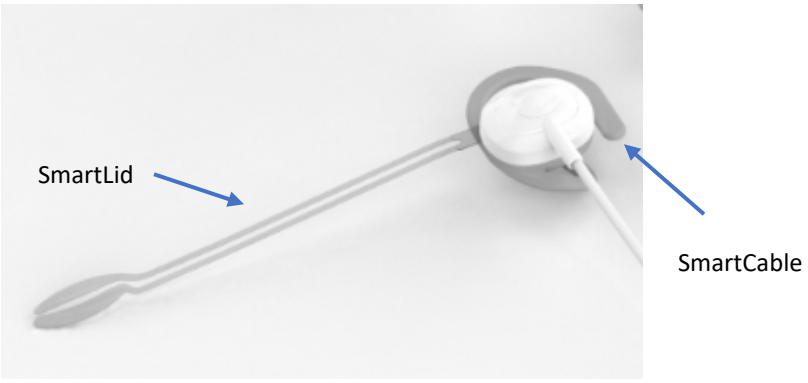

Figure 2, SmartLid® Device Assembly and SmartCable

Charging Nest and Charger Adapter

The SmartHub requires periodic charging from the Charging Nest and Charger Adapter. The Charger Adapter is inserted into the rear of the Charging Base and can remain plugged-into the Charging Base even when charging is not occurring. The Charging Base charges the SmartHub via a proprietary interface in the base of the SmartHub and the Nest.

Figure 3 (left), Charging Nest

Figure 4 (right), SmartHub in Charging Nest

The TearCare MGX System patient applied heating elements remain similar to compared to the predicate TearCare System, however, the user interfaces of the system are redesigned and utilize touchscreen graphics for an intuitive and high-tech aesthetic. A comparison of the technological characteristics between the subject TearCare MGX System compared with the predicate TearCare System device is shown in **Table 1** below.

Table 1Comparison of Technological Characteristics with the Predicate Device

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System 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® 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			
System Components	• TearCare MGX System Kit (P/N 06985) (includes): - TearCare SmartHub (P/N 07066) - SmartCable (P/N 06998) - Charging Nest kit (P/N 07067) - IFU Guide (P/N 06988) • TearCare SmartLids (P/N 07064) - SmartLid consists of: • eyelid flexible heating elements • Earloop	• SmartHub Kit (P/N 06041) (includes): - SmartHub (P/N 07412) - Charging kit (P/N 06124) - IFU Guide (P/N 07418 • SmartLids (P/N 06115) - SmartLid consists of: • eyelid flexible heating elements • Templepad	The TearCare MGX System components have been updated. In the predicate device, the cable was incorporated within the disposable SmartLid assembly. In the subject TearCare MGX System the cable is removed from the SmartLid assembly and is a reusable component, the SmartCable. The cable maintains connection of the SmartLids to the SmartHub similar to the connection present in the predicate device. However, the SmartCable adds an additional interconnect to permit re-use of the cable section for reduced waste.
Device Description	• Disposable SmartLid components are attached to the external surface	• Disposable SmartLid components are attached to the external surface of	

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
	of the eyelids and connect via a reusable SmartCable to the reusable SmartHub touchscreen 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 MGX System	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 System	**Equivalent**
SmartHub therapy control	SmartHub provides control to power on, start, stope, and resume therapy, increase or decrease warmth levels	SmartHub provides control to power on, start, stope, and resume therapy, increase or decrease warmth levels	**Equivalent**
SmartHub user interface	Touchscreen display with graphic user interface (GUI). During a therapy the health care provider can use the GUI to initiate, stop and adjust the warmth setting.	Push-button interface with graphic symbols and light indicators. During a therapy the health care provider can use the push buttons to initiate, stop and adjust the warmth setting.	Use of the predicate TearCare System device requires consultation of the IFU to interpret system status and light indicators. Individual flashing lights or combination of flashing lights of the power button, battery level indicators, timer counter, or SmartLid connection and audible tones provided information on system status and error codes. The TearCare MGX subject device with the graphic user interface provides indication of system status and notification of errors through text description and audible error tones. Additional screens of the TearCare MGX SmartHub display allows for control of additional features present with the display such as system settings, date/time, practice

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
			information, battery charging display, and error log. The functions of the SmartHub regarding therapy control are **Equivalent**.
SmartLids configuration	Eye lid flexible element Ear loop Ear loop housing (connection for reusable SmartCable)	Eye lid flexible element Temple pad housing Wired cable	The eyelid flexible elements are the same size and construction in the TearCare MGX System as in the predicate TearCare System device. SmartLid features proximal to the heated portion have been updated where the temple pad housing that attaches to the patient's temple via adhesive foam has been replaced with an earloop that wraps around the ear. The positioning of the eyelid flexible elements on the patient's eyelids is maintained the same as in the predicate device when the Earloop is secured to the ear with surgical tape. The predicate TearCare System SmartLids configuration contained a wired cable to connect to the SmartHub. The TearCare MGX System SmartLid device has removed the wired cable for direct connection to the SmartHub and replaced with a housing. The housing allows for connection of the SmartCable, an additional component, as detailed above in the "System Components" section. The SmartCable maintains connection and communication of the SmartLids to the SmartHub similar to the connection present in the predicate device. **Equivalent**

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
Sterilization	The TearCare MGX SmartHub and SmartLids are non-sterile	The TearCare SmartHub and SmartLids are non-sterile	**Equivalent**
Single Use or Reusable	• SmartLids: single use • SmartHub and SmartCable: reusable	• SmartLids: single use • SmartHub: 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**
Duration of Treatment	15 minutes of heat treatment with the TearCare MGX System, followed by manual expression of all four eyelids using the Clearance Assistant which typically requires 5-10 minutes. An optional extended warming hold is available following heat treatment to allow flexibility to perform expression while the eyelids are warm.	15 minutes of heat treatment with the TearCare System, followed by manual expression of all four eyelids using the Clearance Assistant which typically requires 5-10 minutes.	**Equivalent** The additional thermal dose of the extended warming time feature does not significantly impact the overall thermal dose of the system as compared to the predicate, and therefore does not impact device safety and effectiveness.
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** Frequency of temperature monitoring for thermistor reading from the SmartLid has increased. This increased monitoring frequency allows for tighter precision of temperature control while the performance output remains the same as the predicate device.

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
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**
Maximum Absolute Temperature Limit during Extended Warming Time	43°C	N/A	Extended Warming Time is set to the same temperature set point as system warmth setting level 1. This maximum temperature limit is the same as level 1 temperature limit as in the predicate. The additional thermal dose of the extended warming time feature does not significantly impact the overall thermal dose of the system as compared to the predicate, and therefore does not impact device safety and effectiveness.

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
			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** The TearCare MGX SmartLid therapy initiation temperature ramp up from baseline has been updated compared to the predicate, but the time limit and set point to reach target warmth level 1 are the same in the subject TearCare MGX device as the predicate.
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	Sealed pouch with sulfur bleached sulfide (SBS) tray	**Equivalent** Accelerated Aging per ASTM F1980-21, Environmental and transit testing per ASTM D4169 and ASTM D4332
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,	Limited contact duration device per 10993-1 Yes, medical-grade silicone/acrylic tape, Polyolefin Foam and polyimide	**Equivalent** Evaluation of materials compliant to 10993-1

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
	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 10993-23, and guinea pig maximization testing per ISO 10993-10.	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.	
	SmartLid – eyelid element materials - Polyimide - Medical-grade silicone/acrylic tape Polyolefin Foam	SmartLid – eyelid element materials - Polyimide - Medical-grade silicone/acrylic tape Polyolefin Foam	
	Earloop materials - Santoprene - Makrolon	N/A	
	N/A	Temple Pad housing materials - 3M Foam Medical Tape (1772) - 3M 467MP adhesive	
Shelf Life	Testing was performed to demonstrate a 25-month shelf life for the SmartLids	Testing was performed to demonstrate a 25-month shelf life for the SmartLids	**Equivalent**

Characteristic	TearCare MGX™ System *Subject Device*	TearCare® System K213045 *Predicate Device*	Comparison between TearCare MGX System and Predicate Device
Thermal Safety	• TearCare MGX System bench testing verified function of thermal safety requirements • Clinical testing measured the corneal and eyelid temperatures to validate thermal safety requirements	• TearCare System bench testing verified function of thermal safety requirements • Clinical testing measured the corneal and eyelid temperatures to validate thermal safety requirements	**Equivalent**
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**

Summary of Testing Performed

The nonclinical bench testing conducted on the TearCare MGX System in accordance with risk analysis and design control requirements included design verification and functional product testing including software validation, sterilization validation, packaging and shelf-life testing, electrical safety testing, and EMC and biocompatibility testing. Results of the nonclinical testing demonstrate that the TearCare MGX System components and accessories meet the design intent and complies with the applicable requirements.

- Thermal and Functional Requirements: The thermal and functional performance of the TearCare MGX SmartHub and SmartLids were evaluated in a benchtop simulated use condition.
- Visual Inspection and Measurement of Physical/Operational Requirements: TearCare MGX system physical and operational requirements were successfully verified by visual inspection or quantified with measurements by calibrated instruments such as a ruler, calipers, scale, and so forth.
- Verification of Component Specifications: Inspection activities were utilized to verify the component specifications and label requirements.
- Mechanical Testing: Testing was performed to demonstrate that the system meets mechanical strength requirements.
- Shipping and Storage: Testing was performed to demonstrate that the TearCare System meets functional requirements after being exposed to shipping and storage conditions.
- Shelf-Life and Packaging Testing: Accelerated aging and functional testing of the TearCare System and its packaging was performed to support a minimum 25-month shelf life for the disposable SmartLids.
- Biocompatibility: All patient-contacting materials were reviewed to confirm that that they are biocompatible for limited exposure (<24 hours), intact skin contact as demonstrated by cytotoxicity testing per ISO 10993-5, and primary skin irritation, repeated patch dermal sensitization, and guinea pig maximization testing per ISO 10993-10. In addition, the eyelid contacting materials that are heated during a TearCare procedure were successfully met the acceptance criteria for intracutaneous irritation and ocular irritation per ISO 10993-10.
- Software Functionality: Software Verification and Validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*" The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.
- Electrical Safety: Testing was performed to demonstrate that the System meets the electrical safety requirements specified in IEC 60601-1.
- Electromagnetic Compatibility: Testing was performed to demonstrate that the System meets the electromagnetic requirements specified in IEC 60601-1-2.

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.

Clinical Validation Study Summary

In addition to bench testing, Sight Sciences performed clinical validation testing of the current TearCare MGX System design to demonstrate in acute clinical study that the temperatures achieved met key performance and safety criteria. A total of 15 adult subjects (30 eyes) were enrolled in the study, 15 females. Testing demonstrated that the TearCare System met the minimum and maximum temperature specifications with 95% confidence and 90% reliability.

There were no adverse events, nor any clinically significant changes observed in slit lamp exams.

A summary of the outer eyelid and corneal tissue temperatures measured at the lowest SmartHub setting is presented in **Table 2** below.

Table 2 Mean Tissue Temperatures at Lowest Temperature Setting (41°C)

	Baseline (°C) Mean ± SD (Range)	**End of Procedure (°C)** Mean ± SD (Range)
Outer Eyelid[a,c]	34.6 ± 0.42 (33.6 – 35.5)	41.2 ± 0.31 (40.1 – 41.8)
Cornea [b,c]	33.7 ± 0.63 (32.3 – 34.8)	35.0 ± 0.70 (33.4 – 36.7)

[a] Measured with thermocouples; includes upper and lower lids
[b] Measured with IR camera
[c] Mean (SD) values are mean of all measurements for upper and lower, OS, and OD for outer eyelids, and mean of all OD and OS measurements for inner eyelids and cornea

A summary of the outer eyelid and corneal tissue temperatures measured at the highest SmartHub temperature setting is presented in **Table 3** below.

Table 3 Mean Tissue Temperatures at Highest Temperature Setting (45°C)

	Baseline (°C) Mean ± SD (Range)	**End of Procedure (°C)** Mean ± SD (Range)
Outer Eyelid[a,c]	33.7 ± 0.56 (32.4 – 35.0)	44.2 ± 0.46 (42.9 – 45.1)
Cornea [b,c]	33.4 ± 0.72 (32.1 – 35.2)	35.6 ± 0.78 (34.0 – 36.9)

[a] Measured with thermocouples; includes upper and lower lids
[b] Measured with IR camera
[c] Mean (SD) values are mean of all measurements for uper and lower, OS, and OD for outer eyelids, and mean of all OD and OS measurements for inner eyelids and cornea

Based on the outer eyelid temperatures, the TearCare MGX System maintains the minimum steady state temperature of the device (41°C ± 2°C) and does not exceed the maximum temperature setting (45°C ± 2°C), as in the predicate TearCare System device. The effectiveness of the device is demonstrated in the final temperature of the outer eyelid targeted at 41-45°C to melt the meibum blocking the meibomian glands, not the difference in temperatures from the baseline. The temperature output of the subject device is substantially equivalent to the predicate.

During the Clinical Validation Study of the TearCare MGX device, three out of 15 subjects noted loose fitment of the earpieces and felt the need to support the earpieces. Therefore, an additional clinical validation study was performed to validate the fit and retention of the TearCare MGX System Earloop using modified Instructions for Use. In this additional clinical validation study, the TearCare MGX System was applied to 21 subjects, and surgical tape was used to secure the Earloop components to both ears of all subjects. All Earloop components remained affixed to the ears in all subjects for the duration of the 25 minute simulated treatment. The results of this additional 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 Earloop component is secured to the head with tape.

Conclusions Drawn from Bench and Clinical Performance Testing

The results of the bench and clinical evaluations demonstrate that the TearCare MGX System is substantially equivalent to the TearCare System.