December 21, 2021

Sight Sciences, Inc.
Edward J. Sinclair
Consultant
4040 Campbell Ave., Suite 100
Menlo Park, CA 94025

Re: K213045
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: September 21, 2021
Received: September 24, 2021

Dear Edward J. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation titled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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, 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)*
K213045

Device Name
TearCare® System

Indications for Use *(Describe)*
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.

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: K213045

510(k) Owner: Sight Sciences, Inc.
4040 Campbell Ave., Suite 100
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Contact Person: Edward J. Sinclair
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Tel: 650-218-9149

Date Prepared: November3, 2021

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: LipiFlow® Thermal Pulsation System
510(k) Holder: Johnson and Johnson (formerly TearScience, Inc.)
510(k) Number: K161357
Clearance Date: November 4, 2016

Indications for Use

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.

Device Description

To use the TearCare System, the flexible SmartLids are applied to the external surface of the upper and lower eyelids of the right and left eye of the patient. The SmartLids are then connected to the SmartHub. When the SmartHub is turned on and the eye care professional initiates the procedure, the TearCare System begins delivering heat to the eyelids. 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 gland orifices. A complete TearCare session lasts 15 minutes.

After TearCare 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 System has not been established when used in conjunction with any other meibomian gland expressor. Effectiveness of the TearCare System has not been established when used without manual meibomian gland expression.

The TearCare System is comprised of the following key components and accessories:

- SmartHub – a reusable component that incorporates hardware and software to power the SmartLids during treatment. The SmartHub has 5 temperature set points (ranging from 41 to 45°C), which allow the user to manually adjust the temperature up or down to a level that is comfortable for the patient. The SmartHub is powered by an internal lithium-ion battery and has an intuitive 4-function, 3-button interface which provides the user the status and control of treatment initiation, treatment temperature setting, remaining treatment duration, and treatment termination.

- Charging Nest - a reusable plastic desktop cradle that holds one SmartHub in order to recharge the SmartHub battery.

- Charging Adapter and Wall Plug - a reusable AC/DC wall-mount adapter that accommodates 80-264 VAC input voltage and provides 9.0 VDC output voltage to the SmartHub through the Charging Nest.

- SmartLids – a single use component of the TearCare System that is designed to conform to the upper and lower eyelid. They contain flexible circuits, sensors and a microprocessor which provide accurate and precise thermal energy to the eyelids to melt oil in the meibomian glands. Medical grade adhesive on the skin-facing surface of the SmartLids allow them to be affixed to the external surface of the eyelids during the procedure and easily removed at the end of the procedure. Each SmartLid is connected to the SmartHub by a cable integrated into the SmartLid. The integrated cable is four feet in length.

A comparison of the technological characteristics between the subject TearCare System compared with the predicate LipiFlow device is shown in Table 1 below.

Table 1. Comparison of Technological Characteristics with the Predicate Device

Characteristic	TearCare® System (Sight Sciences, Inc.) ***Subject Device***	LipiFlow® Thermal Pulsation System (Johnson & Johnson) K161357 ***Predicate Device***
Device Classification	Class II	Class II
Classification Product Code	ORZ	ORZ
Regulation Number	886.5200	886.5200
Indications For Use	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.	The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye
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	• Disposable EyeCup is applied to the outside of the eyelid to automatically apply pressure using a bladder that intermittently inflates with air. The disposable LidWarmer contacts the inner eyelid surface and provides unidirectional heat to the inner eyelid • The Disposable portions connect to a Control Unit • System applies heat and pressure to the eyelids
Sterilization	The TearCare SmartHub and SmartLids are non-sterile	EyeCup/Lid Warmer are provided sterile by ethylene oxide to 10^{-6} SAL
Single Use or Reusable	• SmartLids: single use • SmartHub: reusable	• EyeCup/Lid Warmer: single use • Control Unit: reusable
Operation Control	Eye Care Practitioner	Eye Care Practitioner
Mechanism for Heat Generation	Polymer encapsulated resistive heating element	Resistive (plastic) electric heater
Power source	Batteries, DC power	AC power
Point of Use	In-Office	In-Office
Duration of Treatment	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	12 minutes of heat/pressure treatment
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 surface of the eye is regulated by the Control System

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	42.5°C (constant temperature)
Temperature Accuracy	± 0.7°C	± 0.5°C
Maximum Inner Eyelid Surface Temperature Limit	No inner eyelid sensor or temperature limit	44°C
Maximum Sustainable Therapeutic Temperature (i.e., for the duration of the procedure)	46.74°C	Not reported
Maximum Absolute Temperature Limit (at any exposure time)	47°C	Not reported
Maximum Outer Eyelid Surface Temperature Limit (Safety Limit)	46.99°C for 2 seconds prior to automatic temperature downregulation	No outer eyelid sensor or temperature limit
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)	10 to 60 seconds
Pressure Control	Manual: Eye Care Practitioner, using separately provided expressor forceps determines pressure (based on patient feedback and direct viewing of glands)	Automatic: pre-programmed with some adjustment allowed by Eye Care Professional
Pressure Type	Manual expression using separately provided Clearance Assistant expression forceps	Automatic massage by EyeCup
Treatment of upper and lower eyelids	Concurrent for upper and lower eyelids of both right and left eye	Concurrent
Packaging (pertinent to disposable)	Sealed pouch with sulfur bleached sulfide (SBS) tray	Sealed Tray
Performance Testing		
Biocompatible patient-contacting materials (ISO 10993-1)	Yes, medical-grade silicone/acrylic tape, Polyolefin Foam and polyimide supported by cytotoxicity testing per ISO 10993-5, primary skin irritation, intracutaneous irritation, repeated patch dermal sensitization, guinea pig maximization, and ocular irritation testing per ISO 10993-10	Yes, silicone and UV cured adhesive
Shelf Life	Testing was performed to demonstrate a 25-month shelf life for the SmartLids	Testing was performed to demonstrate a 6-month shelf life for the EyeCup/ LidWarmer
Thermal Safety	• TearCare System bench testing verified function of thermal safety requirements	• Animal testing was performed to measure the peak corneal temperature during use • Clinical testing measured the maximum corneal temperature immediately after

	• Clinical testing measured the corneal, inner and outer eyelid temperatures to validate thermal safety requirements	device use to validate the thermal safety requirements
Software	Testing was performed to verify/validate that the system software met all requirements	Testing performed. Results not publicly available.
Electrical Safety per IEC 60601-1	Meets requirements	Meets requirements
Electromagnetic Compatibility (EMC) per IEC 60601-1-2	Meets requirements	Meets requirements

Summary of Testing Performed

The nonclinical bench testing conducted on the TearCare 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 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 SmartHub and SmartLids were evaluated in a benchtop simulated use condition.
- Visual Inspection and Measurement of Physical/Operational Requirements: TearCare 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 short-term (<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: Testing was performed to demonstrate that the software in the SmartHub and SmartLids meet all software and related user requirements.
- 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 System.

Clinical Validation Study Summary

In addition to bench testing, Sight Sciences performed clinical validation testing of the current TearCare 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, 12 females and 3 males. Testing demonstrated that the TearCare System met the minimum and maximum temperature specifications with 95% confidence and 90% reliability.

One female study subject had a baseline visual acuity of 20/25 in her right eye that decreased to 20/40 immediately after completion of both the low temperature and high temperature tests. No clinical findings were reported in the slit lamp examinations conducted before and after the treatment. The subject was seen two days later, and her visual acuity had improved to 20/20 in the right eye (1 line better compared to baseline). The change in visual acuity noted immediately after TearCare treatment was temporary and was deemed clinically insignificant by the investigator.

There were no other adverse events or clinically significant changes in visual acuity.

A total of 30 SmartLids were tested at the lowest and then the highest temperature settings in 15 Clinical Validation Study subjects (i.e., the left and right eye of each subject). At the lowest temperature setting of the SmartHub, the outer eyelid temperature rose an average of 7.1°C from baseline to the end of the test (from 33.8 to 41.0°C) while the average inner eyelid temperature rose 4.4°C (from 34.3 to 38.7°C). The mean corneal temperature rose 2.2°C during the TearCare procedure when performed at the lowest temperature setting. Post-procedure mean corneal temperature was 36.2°C, while the maximum measured corneal temperature was 37.1°C. A summary of the 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 Tissue Temps (°C) Mean ± SD (Range)	End of Procedure Tissue Temps (°C) Mean ± SD (Range)
Outer Eyelid[a]	33.8 ± 0.7 (32.4 – 35.5)	41.0 ± 0.8 (39.4 – 43.4)
Inner Eyelid[b]	34.3 ± 0.7 (32.9 – 35.3)	38.7 ± 0.8 (37.3 – 40.8)
Cornea[b]	34.0 ± 0.7 (32.3 – 35.2)	36.2 ± 0.5 (35.1 – 37.1)

[a] Measured with thermocouples adhered to the skin-contacting surface of the SmartLid.

[b] Measured with IR camera directed at target tissue.

At the highest temperature setting of the SmartHub, the outer eyelid rose an average of 8.8°C from baseline to the end of test (from 35.0 to 43.8°C) while the average inner eyelid temperature rose 6.0°C (from 35.2 to 41.1°C). The mean corneal temperature rose 1.5°C during the TearCare procedure when performed at the highest temperature setting. Post-procedure mean corneal temperature was 36.4°C, while the maximum measured corneal temperature was 37.1°C. Five minutes after the TearCare procedure was completed, tissue temperatures had returned to within 0.6°C of the baseline temperatures. A summary of the 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)

Tissue Temperatures (°C):	**Baseline** Mean ± SD (Range)	**End of Procedure** Mean ± SD (Range)	**5 Minutes Post-Procedure** Mean ± SD (Range)
Outer Eyelid[a]	35.0 ± 0.9 (32.3 – 36.9)	43.8 ± 0.9 (42.0 – 45.4)	35.6 ± 0.9 (33.0 – 37.5)
Inner Eyelid[b]	35.2 ± 0.7 (33.9 – 36.5)	41.1 ± 0.3 (40.3 – 42.0)	35.8 ± 0.6 (34.1 – 36.8)
Cornea[b]	34.8 ± 0.7 (33.8 – 36.4)	36.4 ± 0.5 (34.8 – 37.1)	35.2 ± 0.6 (33.6 – 36.4)

[a] Measured with thermocouples adhered to the skin-contacting surface of the SmartLid.

[b] Measured with IR camera directed at target tissue.

Corneal temperature increase was minimal and remained within a safe range even at the highest temperature setting of the TearCare System after 15-minute duration. Inner eyelid temperatures demonstrated that the TearCare System maintains a minimum therapeutic temperature even at the lowest temperature setting of the TearCare SmartHub. Ocular tissues returned to near baseline levels within 5 minutes after completion of the TearCare thermal procedure.

Randomized Clinical Trial Summary

A prospective, multicenter, randomized, non-inferiority, masked, controlled clinical trial ("OLYMPIA") was performed to demonstrate the safety and effectiveness of a single TearCare System treatment compared to a single LipiFlow Thermal Pulsation System to treat the signs and symptoms of Dry Eye Disease (DED) in adult patients with Meibomian Gland Dysfunction (MGD). The study results demonstrated that the technological differences between the subject TearCare System and the predicate LipiFlow System do not adversely affect safety and effectiveness as it relates to the indications for use.

A total of 235 subjects (470 eyes) from 10 investigative centers in the United States participated in the study, comprised of 169 female and 66 males, ages 22 to 91 years (mean = 55.9 ± 14.4 years). Subjects were randomized 1:1 to receive either a single TearCare or LipiFlow treatment. Study subjects were grouped into two cohorts to account for a SmartLid design change made during the study. There were 93 subjects in Cohort 1, comprised of 47 LipiFlow and 46 TearCare subjects treated with the prior SmartLid design. There were 142 subjects in Cohort 2, comprised of 73 LipiFlow and 69 TearCare subjects treated with the current SmartLid design. The effectiveness endpoints were assessed using data from Cohort 2 and the safety endpoints were evaluated separately for Cohort 1 and 2.

The primary effectiveness endpoints were defined as the change from baseline to 1 month for Tear Break-up Time (TBUT) and total Meibomian Gland Secretion Score (MGSS) for both treatment groups in Cohort 2. Subjects in both treatment groups demonstrated a statistically significant and clinically meaningful

improvement in TBUT and MGSS at 1-month post-procedure. The TearCare arm of the study established non-inferiority relative to the LipiFlow arm for both TBUT and MGSS.

The secondary endpoints compared the mean change from baseline to 1 month for both treatment groups in Cohort 2 and included: Ocular Surface Disease Index (OSDI), corneal and conjunctival staining scores, and meibomian gland function.

- Dry eye symptoms assessed by OSDI improved with treatment from baseline in both treatment groups.
- Similar and statistically significant decreases in mean corneal and conjunctival staining was demonstrated in both treatment groups.
- Statistically significant improvements in meibomian gland health as assessed by the number of meibomian glands yielding any liquid or the number of glands yielding clear liquid was seen in both groups.

The primary safety endpoint was defined as ocular adverse events (AEs). There were 4 device-related AEs in the TearCare group reported in 3 subjects (Chalazion-1, Superficial Punctate Keratitis-2, Blepharitis-1) and 7 device related AEs in the LipiFlow group reported in 4 subjects (Blepharitis-2, Foreign Body Sensation-3, Dry Eye Disease-2). No serious adverse events (SAEs) were reported in either treatment group. The observed rate of device related AEs was 2.1% (n=2 AEs/92 eyes) and 2.1% (n=3 AEs/138 eyes) respectively in Cohort 1 and Cohort 2 of the TearCare group and 1.0% (n=1 AEs/94 eyes) and 2.1% (n=3 AEs/146 eyes) respectively in Cohort 1 and Cohort 2 of the LipiFlow group. There were 2.1% (n=1 subjects/46) of subjects in Cohort 1 and 4.3% (n=3 subjects/69) of subjects in Cohort 2 experiencing one or more device-related adverse events of the TearCare group and there were 2.1% (n=1 subjects/47) of subjects in Cohort 1 and 4.1% (n=3 subjects/73) of subjects in Cohort 2 of the LipiFlow group. The observed rate of ocular AEs of any type was 4.3% (4 eyes/92 eyes) and 3.0% (4 eyes/138 eyes) respectively in Cohort 1 and Cohort 2 of the TearCare group and 3.2% (3 eyes/94 eyes) and 3.4% (5 eyes/146 eyes) respectively in Cohort 1 and Cohort 2 of the LipiFlow group.

The secondary safety endpoints included measurement of study subject pain and discomfort during and after treatment, change in best corrected visual acuity (BCVA) and change in intraocular pressure (IOP). There were subjects in both groups reporting pain and discomfort during and after the respective procedures. Subjects in the TearCare group initially reported higher pain/discomfort than LipiFlow subjects during and immediately following the procedure. However, by Day 1 the reported pain and discomfort was reduced and TearCare results were less than LipiFlow. Subjects were asked to indicate their level of pain and discomfort using a Visual Analog Scale with “0” indicating no pain/discomfort to “100” indicating worst or maximum pain/discomfort, as shown in Tables 4 and 5 below.

Table 4. Proportion of subjects reporting pain, stratified by treatment arm and cohort

	TearCare				**LipiFlow**		
Pain Thresholds	During Procedure N (%)	During Expression N (%)	After Procedure N (%)	1 day after procedure N (%)	During Procedure N (%)	After Procedure N (%)	1 day after procedure N (%)
	Cohort 1 (n=46)				**Cohort 1 (n=47)**		

0-39	43 (93.5%)	32 (69.6%)	44 (95.7%)	44 (95.7%)	45 (95.7%)	47 (100.0%)	45 (95.7%)
40-69	2 (4.3%)	12 (26.1%)	2 (4.3%)	1 (2.2%)	2 (4.3%)	0 (0.8%)	2 (4.3%)
70-100	1 (2.2%)	2 (4.3%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Cohort 2 (n=69)				**Cohort 2 (n=73)**		
0-39	63 (91.3%)	49 (71.0%)	65 (94.2%)	67 (96.5%)	72 (98.6%)	72 (98.6%)	70 (95.9%)
40-69	4 (5.8%)	16 (23.2%)	4 (5.8%)	2 (2.9%)	1 (1.4%)	1 (1.4%)	2 (2.7%)
70-100	2 (2.9%)	4 (5.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)

Table 5. Proportion of subjects reporting discomfort, stratified by treatment arm and cohort

	TearCare (n=115)				**LipiFlow (n=120)**		
Discomfort Thresholds	During Procedure N (%)	During Expression N (%)	After Procedure N (%)	1 day after procedure N (%)	During Procedure N (%)	After Procedure N (%)	1 day after procedure N (%)
	Cohort 1 (n=46)				**Cohort 1 (n=47)**		
0-39	34 (73.9%)	21 (45.7%)	42 (91.3%)	41 (89.1%)	37 (78.7%)	47 (100.0%)	40 (85.1%)
40-69	11 (23.9%)	17 (37.0%)	4 (8.7%)	4 (8.7%)	10 (21.3%)	0 (0.0%)	6 (12.8%)
70-100	1 (2.2%)	8 (17.4%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	1 (2.1%)
	Cohort 2 (n=69)				**Cohort 2 (n=73)**		
0-39	58 (84.1%)	36 (52.2%)	64 (92.8%)	61 (88.4%)	63 (86.3%)	71 (97.3%)	56 (76.7%)
40-69	9 (13.0%)	27 (39.1%)	5 (7.2%)	7 (10.1%)	9 (12.3%)	2 (2.7%)	13 (17.8%)
70-100	2 (2.9%)	6 (8.7%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	4 (5.5%)

One subject in the Cohort 1 and one subject in Cohort 2 of TearCare group and one in the Cohort 2 of LipiFlow group reported a decrease in visual acuity during the study. One subject treated in the Cohort 1 of TearCare group had a history of visual fluctuation in the right eye. The loss of visual acuity was reported at 2-weeks which was recovered at 1-month visit. A second TearCare study subject treated under Cohort 2 experienced loss of 10 letters at two weeks following treatment and the visual acuity further was reduced by 15 letters at one month compared to baseline. All other ocular findings for this subject were within the normal limits. The investigator suspects an error in visual acuity measurement and reported that it is highly likely that the uncorrected visual acuity was measured in place of best corrected visual acuity. Both AEs were categorized as “unrelated to device or procedure”. One subject treated in the Cohort 2 of LipiFlow group had a history of fluctuating vision in the left eye. The subject read 20 letters at baseline, 30 at 2-weeks and 10 at 1-month. The investigator did not consider this AE as device or procedure related. No other subjects reported any significant visual acuity change in either group compared to baseline.

No significant change in IOP was noted in either group at any follow up visits compared to baseline. The overall safety results are similar between the TearCare System subject device and the LipiFlow System predicate device with respect to the safety profile.

Conclusions Drawn from Bench and Clinical Performance Testing

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