February 09, 2024

CATS Tonometer, LLC
% Omid Khodai, OD, MS, RAC
President
Khodai Consulting, Inc.
23 Bellflower
Lake Forest, California 92630

Re: K234037
Trade/Device Name: CATS-L Tonometer™ Prism
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: December 21, 2023
Received: December 21, 2023

Dear Omid Khodai:

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,

Alexander Beylin 2024.02.09 -S 16:26:22 -05'00'

for Elvin Ng
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)*
K234037

Device Name
CATS-L® Tonometer™ Prism

Indications for Use *(Describe)*
The CATS-L® Tonometer Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure of the human eye.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for the CATS-L Tonometer™ Prism

Submission Sponsor:

CATS Tonometer, LLC
1517 N. Wilmot Road, Suite 143
Tucson, Arizona 85712
Telephone: 520- 975-4550

Contact:

Khodai Consulting, Inc.
23 Bellflower
Lake Forest, CA 92630
Telephone: 949-735-4727
Contact: Omid Khodai, OD, MS, RAC, President
Email: omid@drkhodai.com

Date Prepared:

December 11, 2023

Device Name:

Trade/Proprietary Name:	CATS-L Tonometer™ Prism
Classification Name:	Tonometer and Accessories
Product Code:	HKY
Regulation Number:	21 CFR 886.1930

Predicate Devices:

Predicate Device: CATS-R Tonometer Prism K173904
Reference Device: GOLDEN VISION (Goldmann) Manual Tonometer K981432.

Device Description:

The CATS-L Tonometer Prism is used as an optical image prism for Goldmann applanation style tonometers. The CATS-L prism is made of PMMA, the corneal contact diameter is 6.28 mm, and the total length of the prism is 29.28 mm.

Indications for Use:

The CATS-L® Tonometer Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure of the human eye.

Performance Data:

Five samples of the CATS-L tonometer prisms were evaluated. The test protocol is defined in VP23-001 and the results are reported in the design verification protocol and report. The results are shown in the table below:

Test	Standard	Acceptance Criteria	Result
Area of Applanation	ANSI Z80.10-2018 A1.1	Diameter of 3.06 ± 0.02 mm	Met acceptance criteria
Surface of Pressure Body – surface imperfections	ANSI Z80.10-2018 A1.2	Free from surface imperfections that could damage the eye	Met acceptance criteria
Surface of Pressure Body – Diameter	ANSI Z80.10-2018 A1.2	Diameter minimum of 6.0 mm	Met acceptance criteria
Surface of Pressure Body – Flatness	ANSI Z80.10-2018 A1.6	Flat with a tolerance of 10 or fewer fringes over the 4-mm central diameter	Met acceptance criteria

Substantial Equivalence:

The claim of substantial equivalence to the previously cleared device is supported by the following comparison of characteristics in Table 1 and bench testing. Therefore, the CATS-L Tonometer Prism is substantially equivalent to the predicate devices to the CATS-R Tonometer Prism K173904 and the GOLDEN VISION (Goldmann) Manual Tonometer K981432.

As is shown below in the table, the only difference between the subject device and the predicate device CATS-R Tonometer Prism K173904 is the shape of the prism's ocular contacting surface, minor dimensional differences and the model letter molded into the housing. Shape of the corneal contact surface and dimensions are the same as the other predicate device GOLDEN VISION (Goldmann) Manual Tonometer K981432. Both devices function the same on a tonometer instrument. Model letter molded on the housing serves a cosmetic purpose only.

Design verification bench testing consists of comparing measurements made with the subject tonometer prism design on a reference model eye and demonstrates that measurements meet the requirements of the ANSI Z80.10-2018 Tonometers, Annex A, Reference Tonometers.

Biocompatibility of a product is affected by the materials used in the device and in the manufacturing processes, and both the predicate device CATS-R and the subject device CATS-L are manufactured of the exact same materials and assembled using the same process.

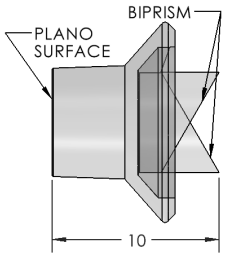
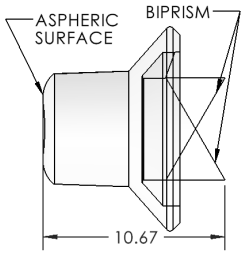
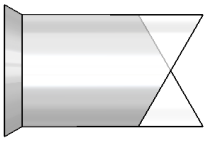
All three parts of the subject and predicate device, the Prism, the Housing, and the Back Plate are manufactured of PMMA, specifically Chimei Acryrex CM-211. The housing has a black colorant added to the Acryrex CM-211. The parts are laser welded together using extra plastic molded on the Housing interface surfaces. The final mass of each device has the same specification, so there is the same amount of material in each device.

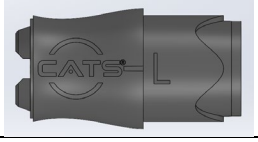
The welded tonometer prism is packaged non-sterile, along with labeling into a small cardboard box. This packaging is the same for both CATS-L, subject device and CATS-R, predicate device. There is no cleaning or disinfecting of the assembled device prior to packaging.

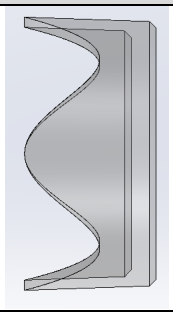
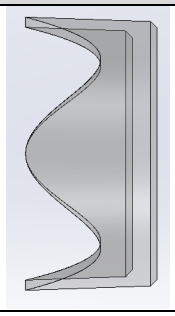
Biocompatibility testing of the predicate device CATS-R device was previously completed and all tests indicated that the device, as manufactured, successfully passed the required testing. Since the subject device CATS-L is manufactured of the same materials using the same manufacturing processes, and packaged in the same packaging (with exception of the labeling model image and details on the box), the results of the biocompatibility testing of the predicate device CATS-R can be safely applied to the subject device CATS-L.

Shelf-life of a product is driven by the materials of the device, the manufacturing process and the other materials used in the processing of the product. A review of Table 1 below, demonstrates that the subject device CATS-L and predicate device CATS-R are essentially the same except for the shape of the prism's ocular contacting surface, dimensional differences and the model letter molded into the Housing. Therefore, it is safe to assume that the shelf-life testing that was completed on the predicate device CATS-R tonometer prism can be applied to the subject device CATS-L device.

Table 1 - Comparison of Subject and Predicate/Reference Devices

Characteristic	Subject Device CATS-L Tonometer Prism	Predicate Device CATS-R Tonometer Prism	Reference Device Goldman Applanation Style Tonometer (GAT) GOLDEN VISION (Goldmann) Manual Tonometer (K981432)
Indications for use	The CATS-L® Tonometer Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure of the human eye.	Same	Same
Sterilization	Non-sterile	Non-sterile (Same)	Non-sterile (Same)
Packaging Design and Materials	Cardboard box	Cardboard box	Cardboard box
Labeling Content	CAT04201 – IFU, CATS-L	CAT04011 – IFU, CATS-R CAT04012 – CATS Accuracy Guide CATS04015 – CATS Inside Lid Label	IFU
PRISM Design (See Below)			
Overall prism length	29.28 mm	29.97 mm	30.0 mm
Prism Base diameter and Front surface	Bi-prism length is 10 mm (per ANSI Z80.10-2018); front surface is Plano (per ANSI Z80.10-2018) 	Bi-prism length is 10.67 mm; front surface is Aspheric. 	Bi-prism length is 10 mm (per ANSI Z80.10-2018); front surface is Plano (per ANSI Z80.10-2018) 

Characteristic	Subject Device CATS-L Tonometer Prism	Predicate Device CATS-R Tonometer Prism	Reference Device Goldman Applanation Style Tonometer (GAT) GOLDEN VISION (Goldmann) Manual Tonometer (K981432)
Prism Back Surface	Biprism	Biprism	Biprism
Contact surface diameter	6.28 mm	6.78 mm	7.0 mm
Bi-prism diameter	6.0 mm	6.0 mm	6.0 mm
Bi-prism length to corneal contact at full applanation diameter	10.0 mm @3.06 mm	10.67 mm @ 3.29 mm	10.0 mm @3.06 mm
Bi-prism angle	30°	30°	30°
Index of refraction	1.4906	1.4906	1.4906
Prism construction material	PMMA (ChiMei Acryrex CM-211)	PMMA (ChiMei Acryrex CM-211)	PMMA
Prism components fastening	Laser welding	Laser welding	Unknown
Prism contact surface	Plano	Concave-convex contoured	Plano
Prism surface finish	Optical polish	Optical polish	Optical polish
Force to IOP Conversion	1.0g = 10mm Hg	1.0g = 10mm Hg	1.0g = 10mm Hg
Applanating area – diameter	3.06 ± 0.02 mm	3.29 ± 0.02 mm	3.06 ± 0.02 mm
Prism Material	PMMA ChiMei Acryrex CM-211	PMMA ChiMei Acryrex CM-211	PMMA
Prism Design	Connected to the housing	Connected to the housing	Connected to the housing
HOUSING Design			Housing is integrated with prism and back plate.
Housing Design	Same except “L” emboss (for Legacy)	Same except “R” emboss (for Reusable)	No Housing. Integrated to a single piece device
Housing Material	ChiMei Acryrex CM-211 with Black colorant	ChiMei Acryrex CM-211 with Black colorant	N/A

Characteristic	Subject Device CATS-L Tonometer Prism	Predicate Device CATS-R Tonometer Prism	Reference Device Goldman Applanation Style Tonometer (GAT) GOLDEN VISION (Goldmann) Manual Tonometer (K981432)
BACK PLATE Design			Back plate is integrated
Back Plate Material	ChiMei Acryrex CM-211	ChiMei Acryrex CM-211	PMMA

Conclusion

Based upon the similarity of the design, material, manufacturing process and the performance characteristics, the CATS-L Tonometer Prism is substantially equivalent to CATS-R Tonometer Prism predicate, cleared under K173904."